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ACTIVE SURVEILLANCE OF BIRTH DEFECTS AMONG US DEPARTMENT OF DEFENSE BENEFICIARIES: REPORT OF A FEASIBILITY STUDY

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Active Surveillance of Birth Defects Among US Department of Defense Beneficiaries: Report of a Feasibility Study

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CONTENTS

EXECUTIVE SUMMARY

Birth defects are responsible for 21% of infant deaths in the United States and are the leading cause of infant mortality. Birth defects in this country are the sixth leading cause of potential life lost and surviving children account for 25-30% of pediatric admissions each year. The combined estimated lifetime cost of treating these conditions is $8.0 billion annually.

As the proportion of women in the military has increased, the number of questions regarding their reproductive health has multiplied. For example, at what point in their pregnancy should women be restricted in their military duty assignment? What occupational exposures are dangerous? The many allegations of reproductive morbidity associated with the Gulf War are well-known examples of increasing concern for both military women and men regarding possible occupational exposures and birth defects. At present, the US Department of Defense (DoD) has few data resources to answer reproductive morbidity and mortality questions.

Although no national US birth defects registry currently exists, 31 states have established birth defects registries. These registries collect comprehensive information on children with birth defects, and such surveillance often leads to epidemiological studies, public health interventions to reduce morbidity, and improved prenatal care. In effect, birth defects surveillance is becoming 'a standard of care' for state public health departments.

State registries cannot be easily used to study birth defects among military families. Few states have access to data in military hospitals. Frequently, civilian hospital data cannot be readily linked to US military populations because the registries often do not retain personal identifying information such as social security numbers. In collaboration with the Centers for Disease Control and Prevention (CDC) and the registry staff of six active surveillance state birth

defects registries, the Naval Health Research Center (NHRC) has developed cutting-edge matching software strategies to use these available data to answer questions regarding birth defects among Gulf War veterans. It has been a very arduous undertaking, involving several years of complex computer analyses and the expertise of several consultants.

In an effort to improve the tools available to study birth defects in military personnel and their beneficiaries, this project sought to determine how the military might best use available data and medical chart review to create a national DoD birth defects registry. Such a DoD registry would provide more timely answers to reproductive questions for health policy decision makers. This feasibility study presents several birth defects surveillance methodologies, examples of birth defects prevalence rates for a specific population, a review of privacy issues concerning birth defects registry data collection, a discussion of future data collection strategies, and recommendations for DoD birth defects surveillance.

Before data collection could begin, considerable effort was made to receive the necessary approval of the Committee for the Protection of Human Subjects (CPHS) at NHRC and the Institutional Review Board (IRB) at Naval Medical Center San Diego (NMCSD). This study received additional examination because it required the inclusion of personal identifiers for database linkages. Realizing the difficulty in obtaining retrospective informed consent from families who had children with birth defects, the investigators requested a waiver from written informed consent from the two committees. Since there were no clear standards for such a waiver and no clear human subject privacy guidance for registry surveillance, much time was spent reviewing federal code and DoD regulations regarding this request. After considerable delays, NHRC's CPHS generated a review of the issues (Appendix H) granting the waiver from

informed consent based on signed privacy act statements in the medical records. This documentation of the committee's rationale may be helpful in the design of other DoD surveillance efforts.

Building upon birth defects registry procedures established by the CDC and the California Birth Defects Monitoring Program, the authors reviewed birth outcome data of military beneficiaries who resided in San Diego County during the period January 1, 1997 through June 30, 1998. Birth defects definitions were based on the CDC's recommended list of diagnostic codes from the International Classification of Diseases, 9th Revision. Several data sources were employed to construct the registry. Active surveillance data collection was based on screening electronic data from the Composite Health Care System, the Ambulatory Data System, and various outpatient paper clinic logs for probable birth defects cases. Subsequently, the personal identifiers for probable birth defects cases were used to pull various inpatient and outpatient medical charts at two San Diego County military medical centers. These charts were reviewed by trained medical abstracters who verified birth defects cases and used computer-guided database software to enter the data.

Civilian confidentiality regulations prohibited access to the medical charts of those beneficiaries who are seen in nonmilitary medical facilities using the benefits of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) system. To capture births and medical encounters with the civilian medical providers, electronic data from CHAMPUS were reviewed. Infants meeting the case criteria were considered cases (without medical chart verification) and added to active surveillance data.

The active surveillance data were compared with data from two types of passive surveillance: a postcard system adapted from that used by health professionals in the United Kingdom and a screening of a new DoD medical database without medical chart verification. Study data demonstrated that the postcard system, despite considerable effort, was not an effective means of identifying probable birth defects. The passive surveillance system used data from Corporate Executive Information System, which tracks all military health care encounters. These data yielded probable cases that, when compared with the active surveillance data, produced a matching rate of approximately 80%. They also identified a few individual cases not captured by active surveillance. The passive system was deemed a viable surveillance method.

Through active and passive surveillance, 5,351 livebirths were screened and 615 individuals with birth defects were identified. Records from these infants with birth defects were further screened for one or more of 43 diagnoses considered by Cowan, with consultation from the CDC, to be major birth defects and of public health importance. A total of 351 major birth defects in 171 individuals were identified. These major birth defects were combined with denominator data (total number of livebirths) from the Defense Manpower Data Center and the Defense Enrollment Eligibility Reporting System to yield a prevalence of 3.2% major birth defects among 5,351 livebirths. This prevalence rate was consistent with birth defects data reported by various states.

To demonstrate the potential of subgroup surveillance, birth defect rate calculations were made for each of the 43 major birth defects diagnoses and by dividing those diagnoses into 17 organ systems groups.

The multiple medical data sources used in this study were independent, complex, and not easily linked. Because the DoD medical database structure is dynamic, much of the researchers' time was spent working with the multiple databases and linking information for specific individuals. At present, the DoD is attempting to make these data more accessible to policy makers.

Realizing that military families are located in many disparate geographical areas and that personnel resources necessary for active surveillance are quite expensive, the authors considered the effectiveness of combining components of active and passive birth defects surveillance in a hybrid system. A passive database screening system with a sensitivity of 80% might be combined with a regional active surveillance system. The active surveillance would permit the collection of comprehensive data not available in the passive system and serve as a validation tool. The active surveillance component would collect demographic data necessary to contact potential participants for future epidemiological study should the passive system identify specific malformations of concern or risk factors, such as occupation or location, that might be associated with increased birth defects incidence. Such a hybrid system would require minimal personnel resources, yet would provide important national DoD data to policy makers.

Objectives

This feasibility study was conducted among US Navy and Marine Corps' personnel and their families with the following objectives:

I. Primary objective:

To create a birth defects registry using active surveillance methods for the period October 1, 1994 through June 30, 1998 for military beneficiaries living in San Diego County. The registry would capture demographic characteristics for the birth defects infant and his/her parents, the type(s) of defect, and date of diagnosis.

II. Secondary objectives:

- Determine the prevalence of major birth defects among livebirths in this population.
- Compare potential passive surveillance systems with active surveillance systems.

Recommendations

1. Create a DoD-wide birth defects registry:

Creating such a registry would meet the recommendations of various expert committees, including the US Senate Committee on Veterans' Affairs and the National Science and Technology Council, and would provide an important mechanism for the DoD to gather data for reproductive health policy decisions. As the registry population increases, it will be possible to: (1) make incidence comparisons over time to assess whether defects rates are stable; (2) guide early intervention; (3) investigate clustering of cases by geographic area, occupation, specific exposures, or deployment; and (4) examine the impact of changes in case definitions, new diagnostic criteria, publicity, or new intervention programs. Providing such a registry would be an important tool for reproductive outcome surveillance. While most states have birth defects registries and such surveillance is becoming a standard of public health care, the majority of state registries do not have access to military birth records.

2. Use a hybrid case finding approach for birth defects surveillance

A hybrid case-finding approach would include passive methodology that screens existing DoD inpatient, outpatient, and CHAMPUS data for infants meeting birth defects definitions. This passive surveillance would be supplemented with aggressive active surveillance methods at NMCSD, the largest DoD medical center. The information gathered during this active surveillance process at NMCSD would be matched to the passive data for the same catchment population and time periods. The percentage of agreement between the active and passive surveillance systems at this one site would be used to estimate the percentage of DoD birth defects collected using the passive system and to indicate if more aggressive data collection is needed. The active system would also permit comprehensive data collection for resultant epidemiological investigations.

By using this hybrid approach, a high proportion of military personnel infants with birth defects will be detected and a birth defects registry created with considerable economic savings in comparison with attempts at conducting active surveillance throughout the DoD.

3. Provide clear authority for DoD birth defects registry surveillance personnel to have access to all related DoD medical beneficiary medical information without the requirement for specific informed consent.

To study birth defects and their prevention, medical surveillance must take place. This surveillance requires the review of large amounts of medical data from military families worldwide. Gaining individual informed consent is not feasible with such vast surveillance.

State birth defects registries often are supported by state legislation permitting their nonconsented review of medical data.

INTRODUCTION

On April 21, 1998, President Clinton signed legislation allocating a 2-year $70 million budget for birth defects research. The legislation reflects the growing interest in preventing birth defects. This interest began with the 3-year Birth Defects Prevention Act of 1992, which expired in 1995. Since that time, birth defects have become the subject of intense congressional committee debate.

Every year in the United States more than 150,000 infants are born with serious birth defects. While improvements in medical care have reduced other causes of infant mortality such as infectious disease, birth defects have become the leading cause of infant death and are the sixth leading cause of potential life lost.[1,2] Until more birth defects can be prevented, the United States will be unable to reduce infant deaths from the current rate of 9.8/1000 births to the Centers for Disease Control and Prevention (CDC) proposed benchmark of 9/1000 births.[3] Children with birth defects account for 25-30% of the pediatric admissions each year. The combined estimated lifetime cost of treating these conditions is $8.0 billion annually.[4]

A *birth defect* is a structural abnormality present, but not necessarily diagnosed, at birth.[1] The majority of birth defects are codified in the range of 740.0 - 759.9 of the International Classification of Diseases, Ninth Revision (ICD-9).[5] Birth defects can be further classified as major or minor. *Major birth defects* are those that affect survival, require substantial medical care, or result in marked physiological or psychological impairment.[1] Structural blemishes and aberrations that are of little or no medical importance are classified as minor.[6] Major birth defects are of far greater medical, social, and fiscal consequence. Birth defects are also classified by their etiology: malformations that involve poor tissue formation, deformations caused by

unusual forces on normal tissues, and disruptions that entail the breakdown of normal tissues.[1] Although many times only a single defect is manifested in an infant, roughly 20-30% of affected infants have multiple defects. Although it is known that some patterns of multiple defects can occur, such as chromosomal abnormalities, the vast majority have no identified underlying pathogenetic or etiologic mechanisms.[1] Approximately 95% of structural birth defects are recognized by a child's first birthday.[7]

Whereas an association between folic acid and neural tube defects has been clearly demonstrated, [8-10] the cause of most birth defects remains unknown. Previous studies have identified an association of birth defects and maternal infections, such as influenza, fever, rubella, and cytomegalovirus [6, 11, 12]; maternal lifestyle, including smoking [13, 14]; alcohol consumption [15, 16]; and use of medications [17]; maternal age [18]; and exposure to various reproductive toxins.[19] Paternal associations include age[20]; exposure to lead and to organic solvents[21]; and employment as a firefighter, printer, janitor, or forestry worker.[22]

The most common birth defects are heart and circulation (1/115 livebirths), muscle and skeleton (1/130), genital and urinary tract (1/135) as compared to spina bifida (1/2000). The mortality rate for birth defects-associated deaths is higher among males than females and higher in blacks than other races.[23] Among those children who die from a birth defect, more than half had a cardiovascular defect, 15% a central nervous system defect, and 12% a chromosomal defect.[23]

The estimates of birth defects vary widely, in large part because of the paucity and quality of data, especially of national US data. The most commonly reported rates are constructed using hospital discharge data. Unfortunately, information from these sources does not capture birth

defects manifested by developmental delay, learning difficulties, conditions such as autism, or those diagnosed in outpatient facilities, including genetics clinics and laboratories. A more inclusive and systematic approach is needed.

One such approach is to conduct surveillance programs. *Surveillance* is the continuous analysis, interpretation, and feedback of systematically collected data. It provides quantitative estimates of the magnitude of a health problem, portrays morbidity trends, and detects epidemics. Surveillance also documents the distribution and spread of health events, facilitates epidemiological and laboratory research, evaluates control and prevention measures (such as public relations campaigns to increase awareness to consume folic acid prior to and during pregnancy), detects changes in health practice, and provides data to plan health-related activities.[24] The ideal surveillance system is flexible, timely, and sensitive with a high positive predictive value (those who are said to have the disease, do have the disease). Because surveillance provides quantitative data, it is an effective response to emotional and potentially explosive issues surrounding the manifestation of disease and possible environmental exposure.

Historically, surveillance has focused on infectious disease. In 1874, the Massachusetts State Board of Health began the systematic reporting of disease in the United States by requesting that physicians provide weekly postcard reports on the prevalent diseases in their practices.[24] Surveillance was largely restricted to monitoring communicable diseases until 1955, when the methodology was employed to identify the vaccine batch that produced paralytic poliomyelitis in 6 children. Birth defects surveillance was precipitated by the global recognition of limb deformations associated with the prenatal thalidomide exposure in the early 1960s.[1]

One surveillance tool that has become increasingly popular, and, with the advent of powerful computers, more feasible, is the registry. A *registry* records all cases of a particular disease or other health conditions in a defined population so that the cases can be related to a population base.[25] Information from multiple sources, such as hospital discharge records, treatment records, laboratory reports, and death certificates, is consolidated for each individual using a unique identification code. Usually a social security number, medical record number, or study identification number is used to ensure that cases are not duplicated. A good registry is composed of several elements: standard, accurate, and precise diagnostic criteria; a structured classification scheme; a population-based approach; and a catchment area with a large number of cases. When data are gathered with these criteria, they can be used to monitor the distribution and trends of morbidity and mortality, to make comparisons with other birth defects registries, and to conduct epidemiological research.[16, 26-29]

Different methods are employed to create and to maintain registries. The two primary approaches are termed active (some use the term intensive) and passive. In the *active* identification system, trained personnel examine multiple data sources in hospitals, clinics, and other medical facilities to collect complete and accurate data in a search for subjects who meet a case definition. The various data that exist in medical charts are abstracted using standard forms (or computer software), reviewed, and assigned a precise diagnosis. *Passive* identification systems identify cases using the diagnostic codes included in vital records or reports submitted to the registry from hospitals, clinics, and other facilities, as well as voluntary (and often sporadic) case reporting by the diagnosing physician.[30] Medical charts are not reviewed to corroborate these cases. The quality and quantity of active surveillance data are generally believed to be

superior to that of passive surveillance data, but they are costlier and labor intensive. Passive systems are not only less expensive, but they also more easily capture data for large populations. Such systems, however, are weakened by lags in reporting time, lack of control over the quality of data, and case underreporting. A hybrid of the two methods is developing. As registry programs have begun to collect data by linking data sets and conducting audits at selected hospitals or other medical care sites where reported rates appear low, the distinction between active and passive ascertainment is beginning to blur. Computer technology has also helped to improve the technique. For example, a variety of existing data sets, such as those extracted from vital records, hospital discharge information, and social services, can be matched to build a composite entry for an individual that may be later modified with data abstracted from a medical chart.

One matching approach is *deterministic matching*. It is based on specific rules, must have complete data in identical formats, and is simple to use. On the other hand, deterministic matching has limited flexibility, requires a sophisticated computer system, and takes time. *Probabilistic matching* is more flexible, accommodates missing data and different types of data, uses less computer time, and generates nonrandom errors. Currently, there are few probabilistic software options. The proposed capabilities of the Department of Defense (DoD) data systems that are soon to be available would permit linking records, using either deterministic or probabilistic matching. In this way, the multiple data sources would provide a means by which to reduce cost, labor, and duplication associated with passive surveillance, while increasing the sensitivity of case finding that is the hallmark of active surveillance.

One of the issues limiting linkage of established civilian defects registries is the lack of a uniform policy governing data collection and variable types. It is also difficult to track individuals as they move from state to state. The CDC Surveillance Guidelines and Standards Committee set a target date of December 1998 to release a draft of the "Surveillance Guidelines and Standards Manual." The CDC hopes that the adoption of uniform standards will permit more comparison and better linkage among state registries.

Several studies have demonstrated that the information recorded on birth certificates does not provide the accuracy needed for effective birth defects surveillance.[2, 31, 32] When birth certificates are electronically recorded, as many are today, it is more difficult to recognize transcription errors before transmission. Additionally, the decreasing length of newborn hospital stays reduces the number of defect diagnoses recorded on the certificate.[31] Although birth certificate data may be imperfect, the approach of using existing data to monitor birth defects is appealing because of its low cost and the sheer volume of data that is created for administrative and billing purposes. The usefulness of such data in conducting research depends on the extent to which uniform diagnostic schemes are used, if supplemental information can be obtained, and the length of time between the health care event and the availability of the data. Now that hospital discharge summaries, including demographic information and discharge diagnoses, are required by the Joint Commission on the Accreditation of Health Care Organizations, such information is routinely collected and stored in a computerized format. The 1996 Health Insurance Portability and Accountability Act mandated additional standardization of the data with the adoption of uniform formats for electronic health care claim transfer between providers

and payers as well as for electronic reporting of managed care. As a result, data linkages are easier and cheaper.

As the military medical system begins to adopt the tools of managed care, the amount of computerized medical data is increasing. The DoD currently collects much of the information needed to conduct a birth defects registry. For example, the DoD collects hospital discharge data in the ICD-9 format. It is standardized and can be compared across systems with other medical facilities. Included in these data are the length of hospital stay, medical discharge diagnosis, social security number, data and place of birth, and period of military service. Because active-duty personnel are required to use military hospitals, this system is a superb source of hospitalization data for this population. The data is available from Corporate Executive Information Systems (CEIS), a subsidiary of Vector Research. Currently, using user-defined queries, CEIS can provide demographic and military medical provider data.

Medical information is increasingly available for those patients seen outside military facilities. When fully operational, the CEIS system will be able to provide outpatient, inpatient, and laboratory data not only for military facilities, but also for military beneficiaries receiving care from civilian providers. In a similar vein, it is possible that a proposed joining of computerized patient records of the DoD, Department of Veterans' Affairs, and the Indian Health Services could be the backbone of future birth defects surveillance, especially if these data, known as the government computer-based patient record (G-CPR), could be linked with the Defense Medical Surveillance System, which is designed to collect detailed medical information on active-duty members.

There are a number of state and national birth defects surveillance programs, employing various methods of case ascertainment and data collection. Currently, 31 states have operational registries, 4 are implementing registries, and 3 are in the planning stage. For example, the California Birth Defects Monitoring Program, established in 1983, collects data from nonfederal hospitals in 11 of 58 counties (San Diego County is not included in the surveillance). Few of the state registries are linked. The only national program is the Birth Defects Monitoring Program, begun in 1974, that includes information from newborn discharge summaries for approximately 1 million, or approximately 25% of annual livebirths in the United States.[1] Prevalence rates are calculated using the number of livebirths as the denominator. The information is not routinely verified and does not include personal identifiers.

Registries have also been created to address certain questions. For example, a Chorionic Villus Sampling (CVS) registry was created following reports, beginning in 1991, that infants of mothers who had the CVS procedure were born with serious limb deficiencies, hemangiomas, and cranial nerve palsies. These registries, much like the numerous cancer and chronic disease registries in the United States, are not easily linked.

The most comprehensive birth defects surveillance in the United States is the Metropolitan Atlanta Congenital Defects Program (MACDP). More than 35,000 births in the metropolitan Atlanta area are reviewed annually and all liveborn and stillborn infants diagnosed with at least one major birth defect by age of 5 years are included. This registry has been used to look at reproductive outcomes of Vietnam veterans and risks for women with insulin-dependent diabetes mellitus. More recently, these registry data have been used to recommend national public health policy. In 1992, the US Public Health Service and the CDC reported that 50-70%

of spina bifida and anencephaly could be prevented if all women of childbearing age consumed daily 0.4 mg of folic acid.[8]

Although several large exploratory studies of reproductive outcomes associated with the Persian Gulf War have been and are currently being conducted, prior to this project a military birth defects registry had not been initiated.[33, 34]

METHODS

Beginning in October 1997, in collaboration with the CDC, the University of California, San Diego, Naval Medical Center San Diego (NMCSD), and Naval Hospital Camp Pendleton (NHCP), the Naval Health Research Center (NHRC) initiated a study to determine the feasibility of establishing a DoD-based active birth defects surveillance program.

Study Subjects

The target population included all livebirths occurring to naval beneficiaries in San Diego County. The two military sites of interest were NMCSD, which is a tertiary referral center for TriCare Region Nine and the largest military hospital in the United States,[35] and NHCP, a 180-bed hospital that provides outpatient and inpatient care for active-duty service members and other military beneficiaries. Because miscarriages, especially those occurring early in the pregnancy, stillbirths, and induced abortions are not uniformly diagnosed and recorded, the denominator for this population was limited to livebirths.

Reproductive Health Care for DoD Beneficiaries

In addition to active-duty members, the Navy provides medical care for dependents of active-duty personnel, retirees and their beneficiaries, and survivor beneficiaries. Family

members who qualify as dependents must be enrolled in the Defense Enrollment Eligibility Reporting System (DEERS) before their claims for care can be processed.

Military gynecologic and obstetric health care is provided through two systems. The obstetric services of military facilities are restricted to active-duty military (defined as regular active duty, cadet/midshipman, guard/reserve) and their dependents. At present more than 90% of San Diego County military births are to active-duty families, implying that the majority of military births take place in military facilities (Personal communication, Ann Marie Muller, Heath Care Support Department, Naval Medical Logistics Command June 26, 1998). The remainder are seen by contracted Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) providers.

CHAMPUS is a cost-sharing health insurance program that assists family members of military personnel in obtaining medical care. Spouses and unmarried children under the age of 21 years (23 if a full-time student) of active-duty individuals are eligible for this program. CHAMPUS is being replaced by TriCare, the DoD's new managed health care plan. TriCare, which operates in every state and overseas location where service members and their families live, provides three levels of service. Option one is a health maintenance organization called "Prime." Military hospitals and clinics provide the majority of the health care and are supplemented by contracted civilian services. Prime does not guarantee that the participant will have access to civilian health care. Option two, "Extra," is a preferred provider organization, in which the cost to the recipient of care is reduced if a TriCare Network Provider is used. Option three, "Standard," is a fee-for-service plan and permits the greatest freedom in selecting a health care provider but also requires the highest beneficiary cost-sharing contributions.

Birth Defect Definitions

A specific case definition was adopted to avoid the introduction of observer or referral bias. An infant with a birth defect was included if the following criteria were met: (1) at least one parent having a residential zip code in San Diego County; (2) the infant's date of birth (or demise) occurred between January 1, 1997, and June 30, 1998; and (3) the infant was diagnosed with at least one birth defect from the MACDP list, which includes more than 1,000 major and minor defects (Appendix A). A *major birth defect* was defined, in this registry, as one of the specific defects proposed by Cowan (with consultation from the CDC) for DoD birth defects surveillance (Appendix B).[33] These definitions were adopted to permit comparison with other registries and other studies.

Laboratory and chromosomal confirmation of diagnoses were recorded in some cases, such as the diagnosis of certain genetic disorders. Most diagnoses of birth defects were based solely on clinical features. Cases were included if the review of actively abstracted medical charts or passively screened ICD-9 diagnoses (when no medical charts were available to validate) met the case definition criteria.

Active Surveillance

Before designing abstraction methods, the scientific literature was reviewed and abstraction forms and guidelines from birth defects registries of other states were collected. These abstraction instruments were reviewed and modified to be consistent with the order of prenatal care forms and charts that make up the medical charts at the hospitals of interest. This

draft instrument was reviewed by Larry Edmonds, Associate Chief for State Services Birth Defects and Genetic Disease Branch, CDC, and then validated on a sample of known cases. The instrument was further refined using feedback gathered during the pretest and it was used to actively abstract actual cases while the data entry program was being beta-tested (Appendix C).

The data entry program based on the instrument was created using Microsoft Visual FoxPro 5.0. The program was a relational database, consisting of 13 tables, most of which were related to the master table where primary case information was recorded and stored. The tables were linked by a study-assigned identification number. Illustrations of the data entry screens are provided in Appendix D. The program checked all case entries to avoid double entry and to determine if any siblings were also in the data set.

While collecting data pertinent to the registry, it was necessary to look not only at information immediately surrounding the birth event but also to track the entire history of the birth defect from initial diagnosis to postnatal treatment. The child's and mother's inpatient charts and the child's outpatient charts were the primary data sources.

The medical records department staff at both study sites were requested to identify patient records containing specific ICD-9 codes that fit the MACDP list, as well as procedure codes such as cardiac catheterization that might indicate a birth defect. These departments used the Composite Health Care System (inpatient) and the Ambulatory Data System (outpatient) to search for probable cases. Subspeciality clinic logs, such as surgery, were also reviewed for possible cases. Once these probable cases were identified, their medical charts were pulled and reviewed by study staff. If necessary, related charts were requested. Birth defect, demographic, prenatal, and postnatal data were gathered from the child's medical charts (inpatient and

outpatient). The mother's inpatient and outpatient medical charts were reviewed for obstetric history, follow-up care, subsequent diagnoses, and general course of care. In general, outpatient charts were found to provide more specific diagnostic information. The infant's outpatient chart permitted the tracking of defects over the first year of life.

To ensure quality data collection, research assistants (abstracters) were trained in case-finding methodology and data recording by an individual with extensive surveillance experience. They were also closely supervised throughout the project. Abstracters routinely backed up their data files and the aggregate registry data were archived on a weekly basis. The abstracted data were further tested for quality by data range checks and by reviewing summary database reports.

Passive Surveillance Using Postcard

A passive postcard notification program was instituted to examine whether using such an inexpensive data collection instrument would facilitate the identification of the infants with the targeted ICD-9 codes. Such a system is routinely and successfully used in the United Kingdom and is used by state health departments in the United States for reportable conditions such as tuberculosis and cholera.

The postcards, modeled on those used in the United Kingdom, were designed to gather demographic and basic diagnostic information (Appendix E) on the child and suspected birth defects. The postcard contained a checklist divided by organ system, which allowed the staff to identify, in general terms, the nature of the birth defects. The postcards were then distributed to the specialty clinics that were likely to have contact with the parents of infants with birth defects, such as the pediatric, obstetric, neonatal, and surgical departments. Medical staff at these clinics

were informed about the notification program and asked to complete a postcard when encountering a child with a suspected birth defect. A member of the abstraction team conducted monthly follow-up telephone calls and made visits to these medical departments to answer questions, to collect competed postcards, and to distribute additional postcards. Suspected cases were followed by the abstracters and included in the registry when the case criteria were met.

Passive Surveillance Using Existing Data Sets

Two DoD-wide databases were studied for use in passive birth defects surveillance. First, we queried CEIS, a database that will eventually include inpatient and outpatient encounters in military treatment facilities. The CEIS Customer Service Division, located at Fort Sam Houston, Texas, responded to our request (Appendix F) for potential cases meeting our birth defects case criteria, as well as information regarding the total number of livebirths recorded by this system. Second, we screened electronic CHAMPUS billing records for all health care encounters with birth defects diagnostic codes. Although there are plans for CEIS to provide extractions from the CHAMPUS data sets (the two organizations are in the process of creating a liaison program), currently CHAMPUS data must be extracted by programmers at CHAMPUS headquarters (this request is included in Appendix G).

The passively acquired data from both CEIS and CHAMPUS were organized and evaluated according to the same standards as the active surveillance system data. Much of the registry consists of data collected using the active surveillance methodology. The active surveillance data were also used to measure the sensitivity (those individuals identified as cases who truly had birth defects) and specificity (those individuals identified as noncases who truly

did not have birth defects) of the passive surveillance data. This validation procedure could be performed on the subset of CHAMPUS data containing those individuals who receive their CHAMPUS benefits in a military facility. It was also conducted on all of the CEIS data. Medical chart data were not available to validate CHAMPUS electronic data. Several infants were found in all three databases and composite entries were created for these cases. The ICD-9 diagnostic codes were checked against the MACDP inclusion list. The date of birth and parents' residences were also confirmed to be within specified parameters. Once the data were determined to have met the case criteria, they were linked to demographic data to provide composite profiles for individuals in the registry.

Statistical Analyses

The data gathered for this surveillance project permitted the generation of descriptive statistics, including an overall as well as specific diagnoses prevalence rates. In order to generate an overall prevalence rate for this population, that is the number of birth defects cases taking place within the defined population, it was necessary to enumerate the population. DEERS census data, which was found to be updated in a more timely and accurate manner than the CEIS or CHAMPUS birth data, was used as the denominator. A number of organ category and specific diagnoses prevalence rates were also calculated. If the surveillance of this population is extended over a period of many months or years, it will then be possible to use these rates to detect clustering, to monitor long-term trends, to assess seasonal patterns, and to project future

occurrence of birth defects. Because of the size of the population* and the duration of the study statistical tests of association were not conducted.

Confidentiality

Confidentiality of individuals involved in research studies may be protected by collecting data in the aggregate and/or by not recording unique identifiers. The very nature of a registry, however, requires using personal identifiers. For example, children with birth defects often receive care at more than one facility. It is important to have identifiers so that each case is only counted once and the estimate of disease occurrence is accurate. CPHS at NHRC spent many hours reviewing our methodology to ensure that the balance between the need to maintain confidentiality and the need to improve public health was preserved. Because surveillance involved children, who cannot grant informed consent, CPHS felt an even stronger obligation to preserve confidentiality. NHRC's CPHS gave the proposal extensive ethical and legal review. A summary of the CPHS' final conclusions is contained in Appendix H.

RESULTS

The active surveillance process began in February 1998. Because of the limitations of the NMCSD computer system, it was necessary to restrict the period of study to January 1, 1997 through June 30, 1998 (18 months). CEIS and CHAMPUS data were screened over the same time period.

*In order to have a 95% confidence level, it would be necessary to have a population with 17,887 livebirths each year.

During this period, a total of 5,351 children with a date of birth between January 1, 1997, and June 30, 1998, were added to DEERS. Thus, 5,351 livebirths was used as the denominator for all rate calculations. A total of 2,515 medical encounters from the three data sources were reviewed and 615 individuals met the birth defects case definition An infant was counted only once for each diagnostic code, regardless of the number of medical encounters he or she may have had for the defect. The number of cases identified in each database and by category are presented in Table 1.

Table 1. Comparison of Major Birth Defects Surveillance Methods, January 1, 1997 through June 30, 1998, N=5,351 Livebirths

Defect Category	Active Surveillance	Passive CEIS Surveillance	Passive CHAMPUS Surveillance
Nervous system	5	6	6
Eye	2	0	2
Ear	1	0	0
Cardiac/vascular	33	29	8
Respiratory	4	3	0
Cleft palate/lip	12	4	3
Upper alimentary	9	5	0
Digestive	4	2	1
Male reproductive	25	7	0
Urinary tract	23	10	1
Musculoskeletal	3	5	1
Limbs	2	0	0

Defect Category	Active Surveillance	Passive CEIS Surveillance	Passive CHAMPUS Surveillance
Chromosomal anomalies	7	4	3

It is important to note that the figures presented in Table 1 represent the total number found in each database, without adjusting for the date of medical encounter. Because there can be up to an 18-month lag period between the medical encounter and entry into CEIS, it was necessary to look at those time periods that had nearly complete data processing. When the active surveillance and the CEIS data were stratified by 3 month periods, January-March, 1997; April-June, 1997; and July-September 1997 (all of which were 90% complete) there was 72% agreement between the sources. Thus, it is estimated that when the data processing is complete, the agreement should be nearly 80%.

Although some individuals appear in all three databases, there will never be total agreement among the databases. The active surveillance and the CEIS should have a high percentage of agreement because they are focused on the same population. The CHAMPUS database, however, includes many individuals seen by civilian health care providers. These individuals will not be part of the active surveillance or the CEIS catchment.

Once the total number of cases in each database were tabulated, the next step was to take the data from all three surveillance methods, combine the cases, and review the diagnoses. At this point, redundant entries were removed. This composite birth defects registry yielded a major birth defects prevalence of 3.2%, which is very similar to national prevalence rates.[1, 6, 29] Rates for the composite birth defects registry are summarized in Table 2.

Table 2. Prevalence of Major Birth Defects, by Organ System, January 1, 1997 - June 30, 1998, N=5,351 Livebirths

Defect Category	Cases	% Cases	Rate	95% CI
Nervous system	15	7.8	2.8	1.4-4.2
Eye	4	2.1	0.7	0.0-1.5
Ear	1	0.5	0.2	0.0-0.6
Cardiac/vascular	63	32.8	11.8	8.9-14.7
Respiratory	4	2.1	0.7	0.0-1.5
Cleft palate/lip	14	7.3	2.6	1.2-4.0
Upper alimentary	11	5.7	2.1	0.8-3.3
Digestive	5	2.6	0.9	0.1-1.8
Male reproductive✠	29	15.1	5.4	3.5-7.4
Urinary tract	25	13.0	4.7	2.8-6.5
Musculoskeletal	9	4.7	1.7	0.6-2.8
Limbs	2	1.0	0.4	0.0-0.9
Chromosomal anomalies	10	5.2	1.9	0.7-3.0

*Rate was expressed as per 1,000 livebirths.

✠There is no category for female reproductive birth defects within the rubric of major birth defects.

The composite birth defects registry data were further stratified by individual ICD-9 codes (Table 3). These data were too sparse to estimate confidence intervals about prevalence estimates.

Table 3- Prevalence of Major Birth Defects, N=5,351 Livebirths

Organ System	Birth Defect	ICD-9 Codes	Cases	Rate
Nervous System	anencephaly	740.0, 740.1	0	NA
	Spina bifida without anencephaly	741.1, 741.9 without 740.0-740.10	0	NA
	hydrocephaly without spina bifida	742.3 without 741.9	11	2.1
	encephalocele	742.0	0	NA
	microcephalus	742.1	7	1.3
Eye	anophthalmia/microphthalmia	743.0, 743.1	8	1.5
	congenital cataract	743.30-.34	12	2.2
	aniridia	743.45	0	0
Ear	anoia/microtia	744.01, 744.23	1	0.2
Cardiovascular	common truncus	745.0	0	NA
	transposition of great arteries	745.10-12, 745.19	3	0.6
	Fallot's tetralogy	745.2	9	1.7
	ventricular septal defect	745.4	30	5.6
	atrial septal defect	745.5	18	3.4
	endocardial cushion defect	745.60-.61, 745.69	6	1.1
	pulmonary valve atresia and stenosis	746.01,746.02	19	3.6
	tricuspid valve atresia and stenosis	746.1	0	NA
	Ebstein's anomaly	746.2	2	0.4
	aortic valve stenosis	746.3	3	0.6
	hypoplastic left heart syndrome	746.7	3	0.6

Organ System	Birth Defect	ICD-9 Codes	Cases	Rate
	coarctation of aorta	747.10	5	0.9
	pulmonary artery anomalies	747.3	11	2.1
Respiratory	choanal atresia	748.0	0	NA
	lung agenesis/hypoplasia	748.5	4	0.7
Cleft Palate/lip	cleft palate without cleft lip	749.00-.04	9	1.7
	cleft lip with and without cleft palate	749.1, 749.2	4	0.7
Upper Alimentary	esophageal atresia/tracheoesophageal fistula	750.3	0	0
	pyloric stenosis	750.5	11	2.1
Digestive	rectal and large intestinal atresia/stenosis	751.2	2	0.4
	Hirschsprung's disease (congenital megacolon)	751.3	2	0.4
	biliary atresia	751.61	1	0.2
Male Reproductive	hypospadias and epispadias	752.6	29	5.4
Urinary Tract	renal agenesis/hypoplasia	753.0	2	0.4
	bladder exstrophy	753.5	1	0.2
	obstructive genitourinary defect	753.2, 753.6	23	4.3
Limb	reduction deformity, upper limbs	755.20-.29	1	0.2
	reduction deformity, lower limbs	755.30-.39	1	0.2
Musculoskeletal	congenital hip dislocation	754.30, 754.31, 754.35	10	1.9

Organ System	Birth Defect	ICD-9 Codes	Cases	Rate
	gastroschisis/omphalocele	756.7	16	3.0
	diaphragmatic hernia	756.6	6	1.1
Chromosomal	Trisomy 13	758.1	2	0.4
	Down's syndrome	758.0	11	2.1
	Trisomy 18	758.2	0	NA

*Rate is expressed per 1,000 livebirths.

The postcard notification program was established at the onset of the study. Research staff visited clinics likely to encounter major birth defects, instructed clinic staff regarding the completion of the postcard, and answered questions about the project. During the 6-month period of active surveillance at NMCSD, a total of 28 postcards were returned, the majority (n=24) coming from the Fetal Assessment Unit. No new cases were identified by this process. The postcard surveillance detected only 17% of the total number of identified cases at NMCSD. Although this program was implemented and did capture accurate information, it did not identify enough cases to supplant or to enrich the active surveillance method.

EVALUATION

Our primary objective in creating an active surveillance birth defects registry was achieved. It is possible to gather the data needed to conduct both active and passive surveillance for births occurring in a DoD beneficiary population.

In conducting this surveillance, we were able to study the nuances of the various departments and agencies involved in the data generating process. As we learned the strengths and weaknesses of each data source, we were able to design an economical data gathering

strategy. The result was a hybrid model that took advantage of the dynamic existing passive disease reporting systems and added comprehensive local active surveillance. Such a hybrid system will permit validation of the passively reported data and preserve an active surveillance system's ability to look more closely at specific birth defects issues.

The desire to create a registry and to conduct surveillance raised important confidentiality issues regarding the inclusion of personal identifiers, an issue that will continue to be debated as more and more medical records are computerized. Following a comprehensive review of the issues, it was decided that this study met the definition of surveillance and that an intrinsic part of surveillance is the ability to track individuals. Our CPHS's written deliberation and recognition of our need to access such data may be helpful for other DoD surveillance projects. A more definitive directive, regulation, or law, however, would certainly aid researchers in gathering future data and legal opinion is being sought to determine the form such a directive should take.

Finally, we have had the active support of health care providers. They strongly welcomed our objective of creating a birth defects registry and mirrored our desire to examine the aggregate statistics. They appreciated our desire to bridge the gap between a research and a clinical environment. They expressed tremendous interest in the future dissemination of aggregate birth defects statistics, which will form the basis of communication about any changes in birth defects occurrence, stimulate research, and improve clinical practice.

LIMITATIONS

This pilot project has a number of data limitations. Birth defects registries often have data limitations due to the time lag between the occurrence of the event and its inclusion in the

registry. Such a time lag could hinder immediate identification of important clusters of birth defects cases. As the efficiency of reporting improves, however, this time lag will continue to be reduced. We saw examples of such improvements. Toward the end of this study, many of the medical charts abstracted were merely weeks old.

These data are further limited by the accuracy of numerator and denominator data. Only livebirths were included in our denominator. An estimated 22% of pregnancies are lost subclinically and an estimated 15-20% of recognized pregnancies result in spontaneous abortion. Such early pregnancy losses may reflect nonviability of the fetus due to chromosomal anomalies (these infants would have had birth defects had they survived to term). Finally, our data were limited to birth defects detected within the first year of life. Birth defects detected later would have been missed.

There are also limitations to working with existing data sets that have been collected for other reasons, such as for billing. First, the analysis is dependent on the quality and completeness of the recorded transactions. Also, such data may not include demographic data necessary to address a study's specific hypotheses. For example, CHAMPUS data do not contain a variable for race or ethnicity and because no civilian medical charts were available for review, CHAMPUS data could not easily be validated or supplemented. Moreover, timeliness of information is particularly problematic for CHAMPUS records. There can be as much as an 18-month delay in completing CHAMPUS database construction.

Using existing vital records, such as birth and death certificates, to identify possible missed cases was deemed to be inefficient. The amount of information this process would have yielded was determined to be insignificant when evaluated in terms of the time and the resources

it required. The New York Congenital Malformations Registry matched vital records to its registry to identify unreported cases. The staff found that this technique increased the statewide prevalence of major malformations by 1.7%, from 416.5 to 423.4 per 10,000 livebirths. They concluded the small number of identified new cases did not justify the amount of resources used to augment the registry.[36] Moreover, unlike the New York population, all Navy beneficiaries have to be registered with DEERS in order to receive health care. Given the availability of this data source, sorting through vital records was deemed unnecessary.

Finally, there are data limitations particular to military health care. In the military system, medical charts are often moved from facility to facility as service members are transferred. Patients carry their outpatient medical charts and sometimes inpatient charts are removed from the treatment facilities. Thus, the paper medical charts needed for abstraction were not always available.

It was surprisingly difficult to quantify populations at risk. Different information sources provided much different denominator data, in part because pregnancies have not been routinely tracked. For example, the Navy does not keep statistics on the total number of female officers who become pregnant while assigned to ships. It was necessary to link a number of data sources in order to examine birth defects among subpopulations.

The variability of coding procedures may also affect case ascertainment. The military has not put the same focus on coding procedures as civilian, revenue-based hospitals do. Because of changes in the military system, however, the diagnostic codes are now receiving increased attention. The quality of this data will continue to improve in the future.

CONCLUSIONS

This project has demonstrated that it is possible to construct a registry of birth defects infants among military beneficiaries. While the data from such a registry have a number of important limitations, projected improvements in DoD health data will gradually improve birth defects estimates. These estimates will provide an important foundation for DoD reproductive health policy decisions.

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Appendix A

Metropolitan Atlanta Congenital Defects Program
Abridged Case Inclusion List

ICD-9 Code	Diagnosis
228.1	cystic hygroma
259.4.1	dwarfism
352.6	Möbius syndrome
331.3-331.7	communicating hydrocephalus; obstructive hydrochephalus; cerebral degeneration
560.8-560.9	intestinal obstruction
634.0-634.9	spontaneous abortions: includes miscarriages
635.0-635.9	legally induced abortions: includes elective and therapeutic
636.0-636.9	illegally induced abortions
637.0-637.9	unspecified abortions
655.00-655.03	central nervous system abnormality in fetus
655.1-655.13	chromosomal abnormality in fetus
655.30-655.33	damage to fetus from viral disease
655.40-655.43	damage to fetus from alcohol addiction
656.40-656.43	intrauterine death after 22 weeks
658.80-658.83	amniotic bands
740.0-759.9	congenital anomalies excluding: 744.1 744.83 744.84 747.0 750.0 752.51 752.52 754.30-754.35 754.50-754.79 757.32-757.39 757.6
760.77	fetal alcohol syndrome
762.3	twin to twin transfer
779.6	termination of pregnancy
779.9	fetal death, stillborn
795.2	abnormal karyotype

798.0-798.9	death
V27.1	single stillborn
V27.3	twins, one liveborn and one stillborn
V27.4	twins, both stillborn
V27.6	other multiple births, some stillborn
V27.7	other multiple births, all stillborn
V32.00-V32.21	twin mate stillborn
V35.00-V35.21	other multiple, mates all stillborn
V36.00-V36.21	other multiple, mates live and stillborn

Appendix B

The Major Birth Defects Suggested by Cowan

Organ System	Birth defect	ICD-9 Code
Nervous system	anencephaly	740.0, 740.1
	Spina bifida without anencephalus	741.1, 741.9 without 740.00-740.10
	hydrocephalus without spina bifida	742.3 without 741.9
	encephalocele	742.0
	microcephaly	742.1
Eye	anophthalmia/microphthalmia	743.0, 743.1
	congenital cataract	743.30-743.34
	aniridia	743.45
Ear	anotia/microtia	744.01, 744.23
Cardiovascular	common truncus	745.0
	transposition of great arteries	745.10-745.12, 745.19
	Fallot's tetralogy	745.2
	ventricular septal defect	745.4
	atrial septal defect	745.5
	endocardial cushion defect	745.60-745.61, 745.69
	pulmonary valve atresia and stenosis	746.01,746.02

Organ System	Birth defect	ICD-9 Code
	tricuspid valve atresia and stenosis	746.1
	Ebstein's anomaly	746.2
	aortic valve stenosis	746.3
	hypoplastic left heart syndrome	746.7
	coarctation of aorta	747.10
	pulmonary artery anomalies	747.3
Respiratory	lung agenesis/hypoplasia	748.5
	choanal atresia	748.0
	lung agenesis/hypoplasia	748.5
Cleft palate/lip	cleft palate without cleft lip	749.00-749.04
	cleft lip with and without cleft palate	749.1, 749.2
Upper alimentary	esophageal atresia/tracheoesophageal fistula	750.3
	pyloric stenosis	750.5
Digestive	rectal and large intestinal atresia/stenosis	751.2
	Hirschsprung's disease (congenital megacolon)	751.3
	biliary atresia	751.61
Male reproductive	hypospadias and epispadias	752.6

Organ System	Birth defect	ICD-9 Code
Urinary tract	renal agenesis/hypoplasia	753.0
	bladder exstrophy	753.5
	obstructive genitourinary defect	753.2, 753.6
Limb	reduction deformity, upper limbs	755.20-755.29
	reduction deformity, lower limbs	755.30-755.39
Musculoskeletal	congenital hip dislocation	754.30, 754.31, 754.35
	gastroschisis/omphalocele	756.7
	diaphragmatic hernia	756.6
Chromosomal	trisomy 13	758.1
	Down's syndrome	758.0
	trisomy 18	758.2

Appendix C

Active Surveillance Abstraction Instrument

MILITARY CONGENITAL DEFECTS REGISTRY CASE RECORD

[redacted]

A. PROCESSING SECTION *FLAGS:*

CASE ID#[redacted]
CHILD'S MEDICAL RECORD PERIOD:
BEGINNING[redacted]

RECORD SOURCE		
SITE	TYPE	ID#
NMCSD		[redacted]

CHILD'S INFORMATION: ABSTRACTER 1 ID# [redacted] ABSTRACTED: 4/13/98
MOTHER'S INFORMATION: ABSTRACTER 2 ID# [redacted] ABSTRACTED: 4/14/98
FATHER'S INFORMATION: ABSTRACTER 3 ID# [redacted] ABSTRACTED: 4/14/98

DIAGNOSTIC SUMMARY DESCRIPTION	SUMMARY CODE (ICD-9)	CERTAINTY	ETIOLOGY	PRE-NATAL DX	POST-NATAL EXAM
1. K/O TURNER'S SYNDROME	758.6				✓
2. CONGENITAL INSUFFICIENCY OF AORTIC VALVE	746.4				✓
3. CONGENITAL ANOMALIES OF HEART	746.89				
4.					
5.					
6.					

COMMENTS:(*NOTE IRREGULARITIES/ABSTRACTION COMPLEXITY/MISSING VITAL INFORMATION)*

1.
2. PT WILL RECEIVE FOLLOW UP CARE AT NHCP,
3. FIRST WEEK IN MAY FOR CARDIAC CARE.
4. ECHO ETC.
5.
6.
7.

EVALUATION PLAN

REPORTING SOURCE	DATE OF NOTIFICATION	IS THIS A REPEAT NOTIFICATION? Y or (N)
RETROSPECTIVE REVIEW MK		

IS THIS A CASE? Y

CASE ID#_____

DEMOGRAPHIC INFORMATION

CHILD'S NAME: LAST:[redacted] SEX: F
FIRST:[redacted] RACE: W
MIDDLE:[redacted] ETHNICITY: H

RESIDENCE AT BIRTH: STREET ADDRESS [redacted] APT# [redacted]
CITY [redacted] COUNTRY [redacted]
STATE or PROVINCE [redacted] ZIP [redacted]

INFANT LIVES WITH: MOTHER + FATHER

MOTHER'S NAME: [redacted] D.O.B [redacted]
MAIDEN NAME: [redacted] SSN: [redacted]
CURRENT RESIDENCE: STREET ADDRESS [redacted] APT# [redacted]
CITY [redacted] COUNTRY [redacted]
STATE or PROVINCE [redacted] ZIP [redacted]
PHONE: [redacted]

RACE: W EMPLOYER: UNKNOWN.
ETHNICITY: H POSITION:
EDUCATION: INSURANCE: ID#

MILITARY SERVICE: MEMBER or (DEPENDENT) BRANCH: VSN
ACTIVE or RETIRED RANK:
D.O.S. __/__/__ TO __/__/__ *(PRES.=99/99/99)* RATE: E4

FATHER'S NAME: [redacted] D.O.B. [redacted]
SSN: [redacted]
CURRENT RESIDENCE: STREET ADDRESS [redacted] APT#
CITY [redacted] COUNTRY [redacted]
STATE or PROVINCE [redacted] ZIP [redacted]
PHONE: [redacted]

RACE: W EMPLOYER:
ETHNICITY: H POSITION:
EDUCATION: INSURANCE: ID#

MILITARY SERVICE: (MEMBER) or DEPENDENT BRANCH: VSN
(ACTIVE) or RETIRED RANK:
D.O.S. __/__/__ TO __/__/__ *(PRES.= 99/99/99)* RATE: E4

CASE ID#

MATERNAL INFORMATION

NAME: [redacted]
SSN: [redacted]
D.O.B.: 12/29/97

AGE AT BIRTH: 19

PREVIOUS PREGNANCIES (*Not including index pregnancy*):

GRAVIDA: 2
PARITY: 1

NUMBER OF ABORTIONS: 0
(INDUCED)

WHICH PREGNANCY	DELIVERY DATE	SEX	BABY'S WEIGHT LBS	BABY'S WEIGHT OZ	GESTATIONAL AGE (WEEKS)	OUTCOME	PLURALITY (Y or N)
FIRST	8-1-95	M	8	0	36	SVD	N
SECOND							
THIRD							
FOURTH							
FIFTH							
SIXTH							
SEVENTH							

INTRAUTERINE EXPOSURES:

USE OF PREGNANCY ENHANCERS/ INDUCERS:
1. 3.
2. NONE 4.

USE OF ALCOHOL: Y or (N)
HOW MUCH/HOW OFTEN:
WHICH TRIMESTER:
(*include all that apply*)

DID MOTHER USE OTC/ PRESCRIPTION DRUGS?
IF "YES," LIST BELOW. Y or (N)

USE OF TOBACCO: Y or (N)
HOW MUCH/HOW OFTEN:
WHICH TRIMESTER(S):

Rx/STRENGTH	*REASON FOR DRUG*	*TRIMESTER(S)*

CASE ID#_____

MATERNAL HISTORY Cont'd.

OBSTETRICIAN: UNKNOWN

PRENATAL CARE: (Y) or N **MONTH CARE BEGAN:** 3 **NUMBER OF PRENATAL VISITS:** 8

ILLNESSES/CONDITIONS/COMPLICATIONS/PROCEDURES PRIOR TO PREGNANCY?

1.
2.
3.

ILLNESSES/COMPLICATIONS DURING PREGNANCY?

1. FETAL ASCITES
2.
3.

COMPLICATIONS DURING LABOR and/or DELIVERY?

1. UMBILICAL CORD
2.
3.

METHOD OF DELIVERY? VAGINAL or CESAREAN SECTION Low Transverse C-S.

IF C-SECTION, INDICATIONS: ____ Abnormal Presentation ____ Cephalic/Pelvic Disproportion
____ Fetal Distress ____ Failed Induction ____ Elective Repeat
✓ Other: FETAL ASCITES.

OTHER COMMENTS:

CASE ID#_____

PATERNAL INFORMATION

[redacted]

AGE AT CHILD'S BIRTH: 24

TERATOGENIC EXPOSURE

USE OF ALCOHOL: Y or N (TIME OF CONCEPTION) HOW MUCH/HOW OFTEN:_____ _____ UNKNOWN
USE OF TOBACCO: Y or N (AT TIME OF CONCEPTION & THROUGHOUT PREGNANCY) HOW MUCH/HOW OFTEN: _____ _____ _____ UNKNOWN

OTHER COMMENTS:

NO AVAILABLE PATERNAL HX
~~AV.~~ IN CHARTS.

CASE ID#_____

CHILD'S INFORMATION

NAME: [redacted] D.O.B.: [redacted]

MOTHER'S NAME: [redacted] MOTHER'S SSN: [redacted]
MAIDEN NAME: [redacted]

FATHER'S NAME [redacted] FATHER'S SSN: [redacted]

BIRTH INFORMATION:

D.O.B. 12/29/97
BABY'S CHART NUMBER: [redacted]
MOTHER'S CHART NUMBER: [redacted]
HOSPITAL OF BIRTH: NMC SD
OBSTETRICIAN: _____ phone _____
PEDIATRICIAN: _____ phone _____

SEX: F
BIRTH WEIGHT: 4062 g _____ lbs _____ oz
HEAD CIRCUMFERENCE: 35 cm _____ in
LENGTH: 20 cm _____ in
DELIVERY OUTCOME: E C/S

APGAR SCORE: 8 1 MIN 9 5 MIN

WAS THIS A MULTIPLE BIRTH? Y or (N)
MULTIPLE BIRTH OUTCOME: CO-TWIN_____ CO-TRIPLET_____
MULTIPLE BIRTH SEX: CO-TWIN_____ CO-TRIPLET_____
MULTIPLE BIRTH CONCORDANCE: CO-TWIN_____ CO-TRIPLET_____

GESTATIONAL AGE: 37+1
NEONATAL EXAM: ✓
ULTRASOUND: ✓
DATE OF LMP: 4/13/97
TYPE OF EXAM: _____
DATE OF ULTRASOUND: __/__/__
EDC: 1/18/97

DID THIS CHILD DIE SECONDARY TO BIRTH DEFECTS? Y or (N)
DATE OF DEATH: __/__/__
PLACE OF DEATH: _____
AUTOPSY: _____

PRENATAL DIAGNOSTICS:

INDEX	PURPOSE	DATE	PLACE	OUTCOME	SPECIFIC RESULTS
KARYOTYPE			NMCSD	WNL	46 XX
FETAL MRI			NMCSD	WNL	ABDOMINAL ASCITES AND REDUN
					ANT MYCHA
AMNIO CENTESIS	AB MRI	12/29/97	NMCSD	WNL	NORMAL FOR MATURITY COR
AMNIO CENTESIS	"	11-5-97	NMCSD	"	
UMBILICAL BLOOD	SAMPLING	11-5-97	NMCSD	"	
FETAL ECHOCARDIOGRAM		10-3-97	NMCSD	ABNL.	FETAL HYDROPS

BOTH REFERENCED IN CHART, NO RECORDS OF TESTS. DEFINITELY DONE BUT NO DOCUMENTATION.

PRENATAL PROCEDURES

DESCRIPTION	DATE	TRIMESTER	SPECIFIC RESULTS

MRI 12/17/97 NMCSD NORMAL – NO EVIDENCE OF INTRA-ABDOMINAL ABNORMALITY.

CASE ID#_____

CHILD'S INFO/HISTORY Cont'd

POSTNATAL SECTION:

POSTNATAL COMPLICATIONS

COMPLICATION	ONSET	~~RESOLVED~~
REDUNDANT NUCHAL FOLD	12/29/97	
SYSTOLIC MURMUR	12/29/97.	
TACHYPNEA	12/29/97.	
ABDOMINAL ASCITES	12/29/97.	
MILK PROTEIN ALLERGIES	2/3/97.	

PHYSICAL EXAMINATIONS

EXAM	DATE	PLACE	OUTCOME	PHYSICIAN'S NAME
1	12/29	NMCSD	CONFIRMED NUCHAL FOLD	CORTES.
	12/29	"	BROAD NASAL BRIDGE	"
	12/29	NMCSD.	RELAXED POSTERIOR EARS.	"
	12/29	NMCSD	WIDENED NIPPLES.	"
	1-5-98	NMCSD	R/O TURNER'S SYNDROME	KL JONES.
	2-3-97	"	BLOOD NOTED IN STOOL.	FAZIL.

POSTNATAL PROCEDURES AND TREATMENTS

PROCEDURE	DATE	PHYSICIAN	OUT-COME	SPECIFIC RESULTS
ECHOCARDIOGRAM X3	12/30/97	JENSEN	AB.	PDA, VSD.
AMNIOCENTESIS	12/25/97	JENSEN		AT BIRTH - LUNG MATURITY CONFIRMED C/SECTION INITIATED.

MEDICATIONS

DRUG/STRENGTH	BEGIN DATE	END DATE

NUTRITION

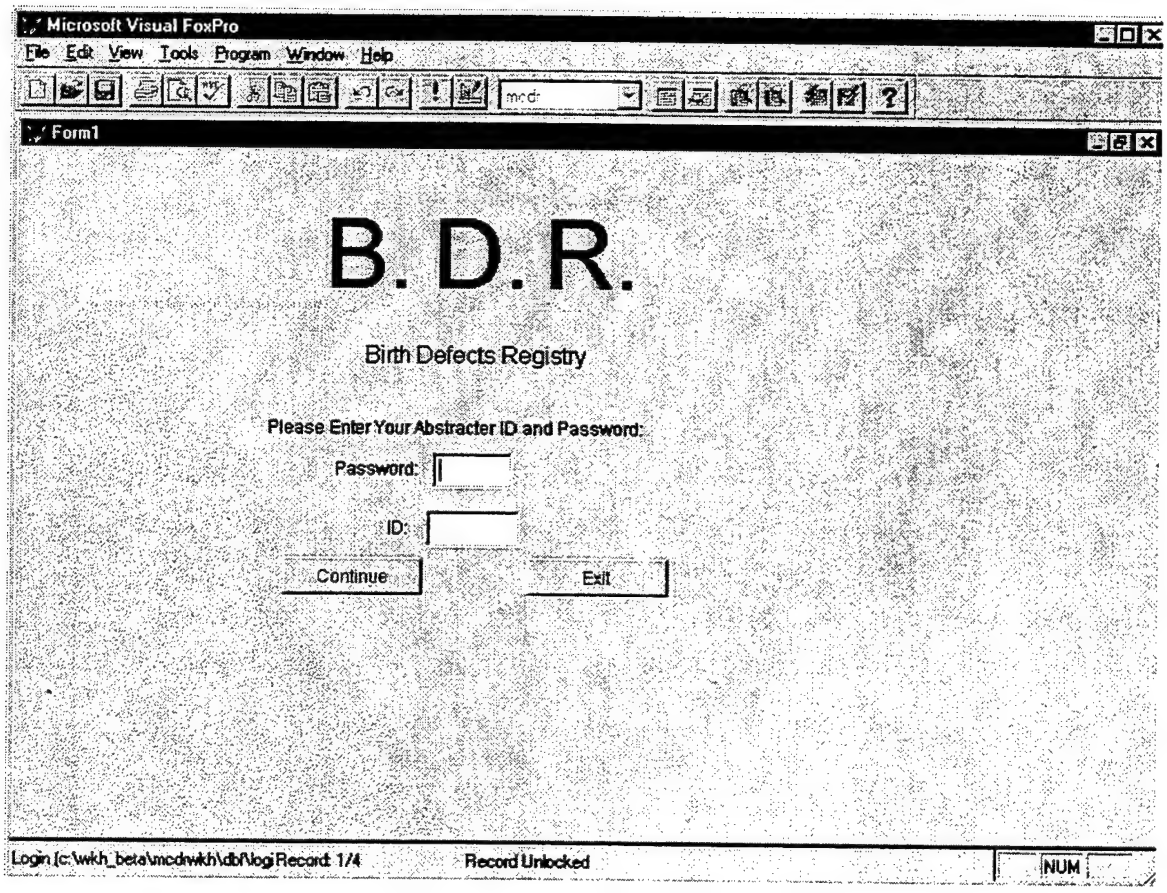
CHILD RECEIVING BREAST MILK? Y or N
FORMULA_____

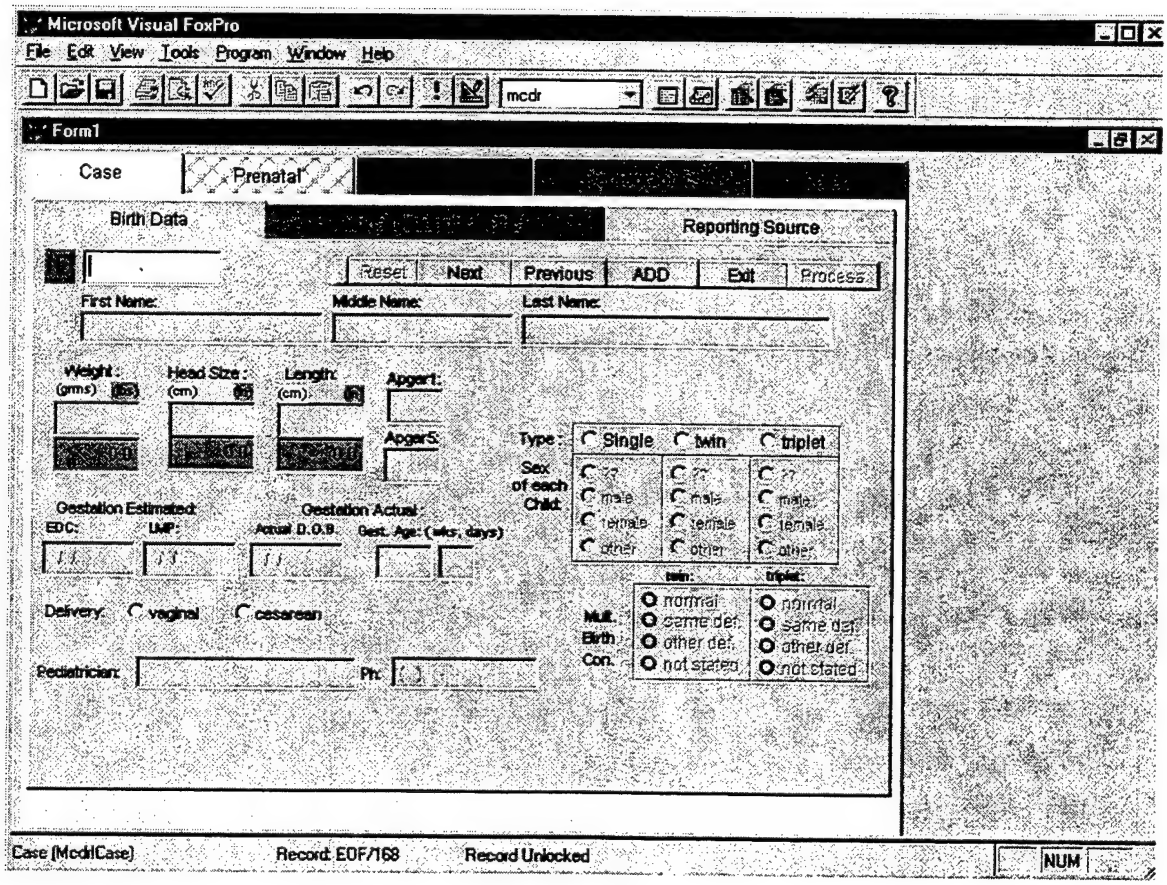
DESCRIBE IF DIET IS APPROPRIATE FOR AGE.

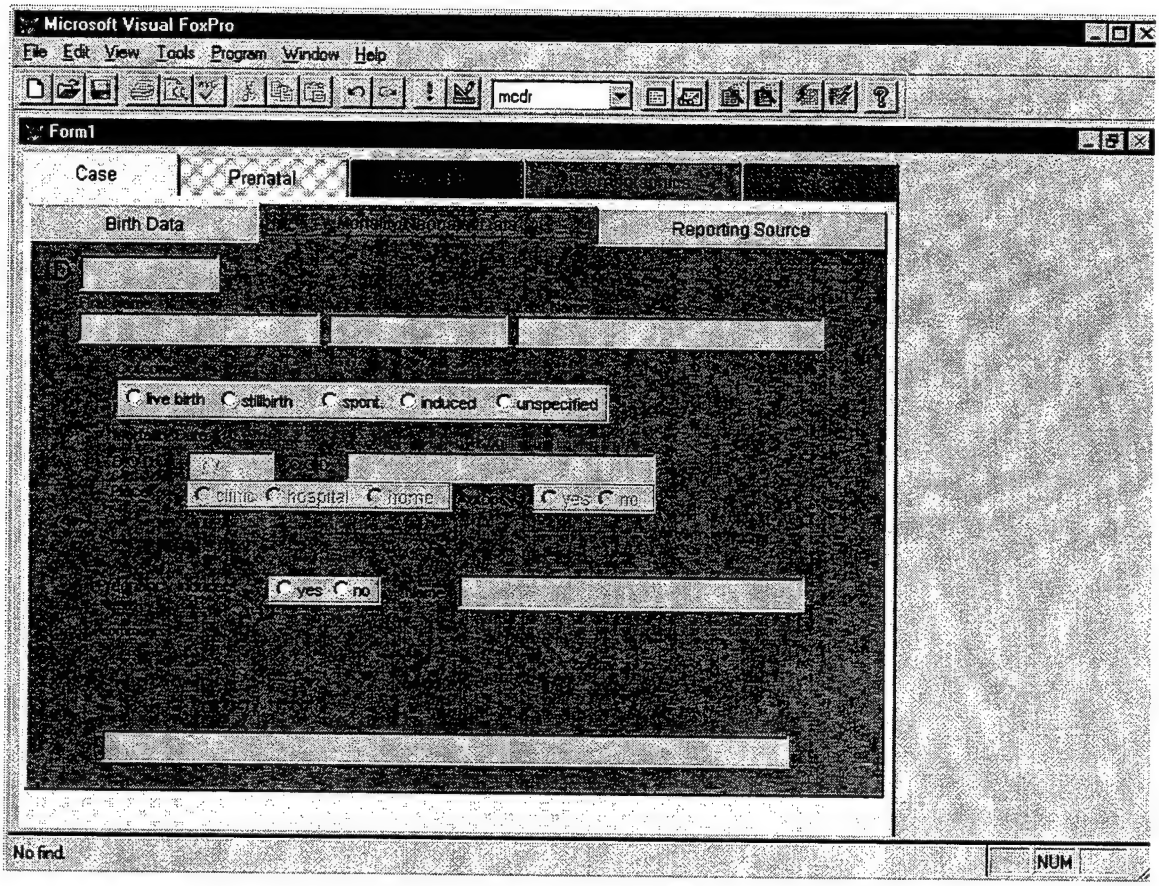
INITIALLY, CHANGED TO SOY - MILK PROTEIN ALLERGY SUSPECTED.

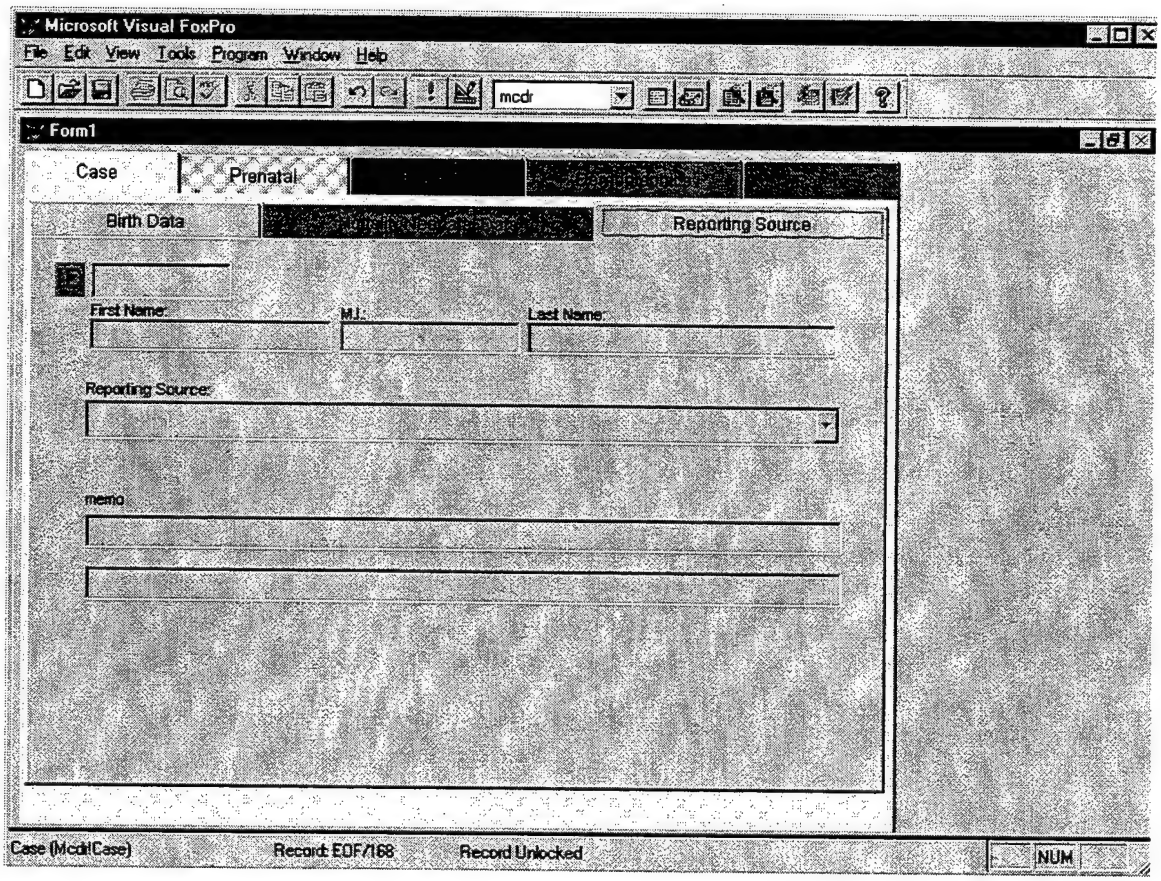
Appendix D

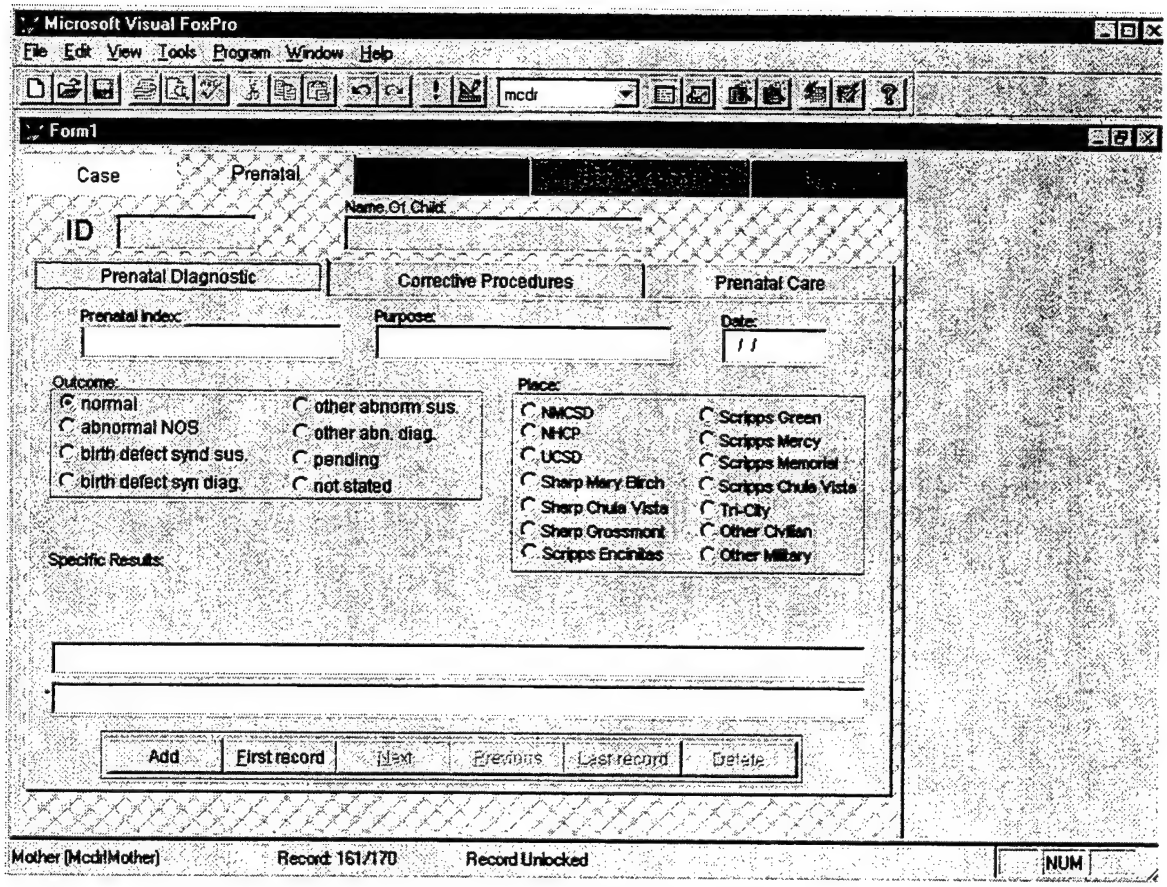
Illustration of
Computer Abstraction Software

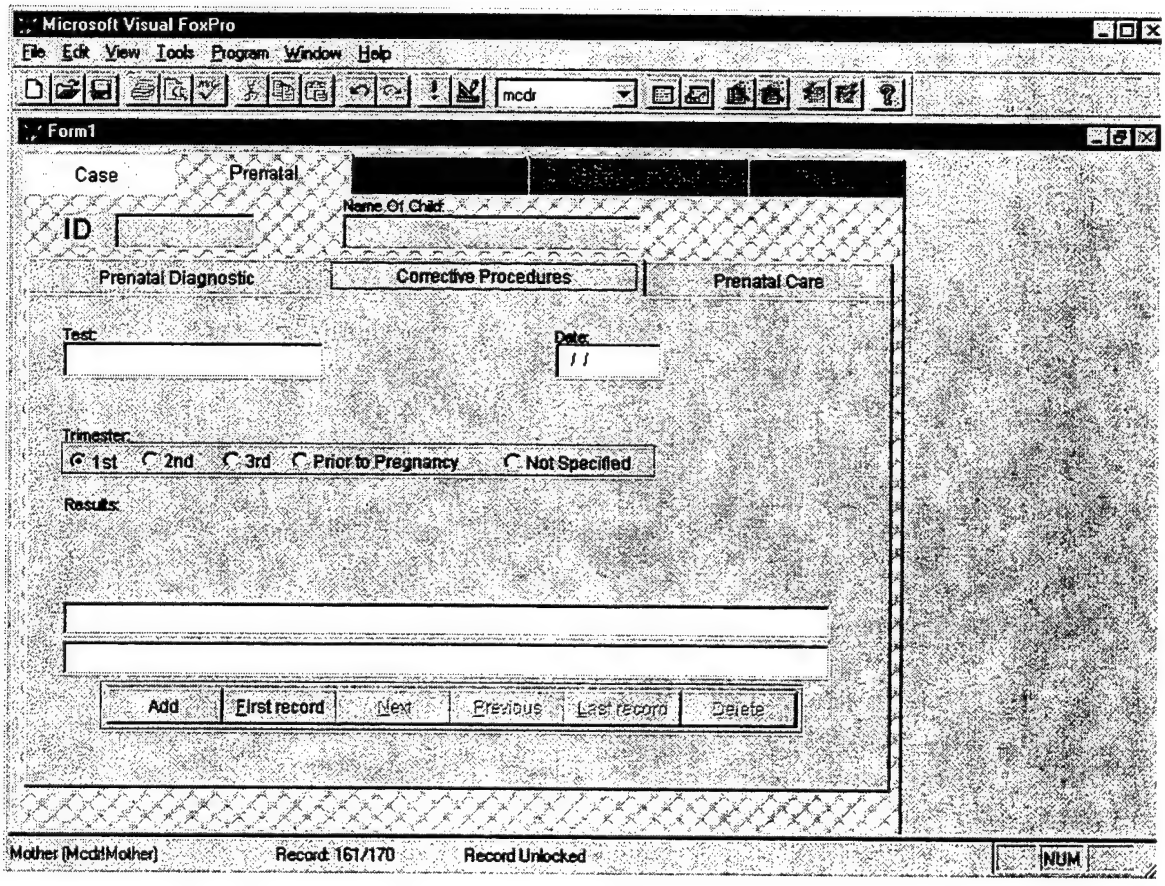

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
B. D. R.
Birth Defects Registry
Please Enter Your Abstracter ID and Password:
Password:
ID:
Continue
Exit
Login (c:\wkh_beta\mcdrwkh\db\log Record: 1/4
Record Unlocked
NUM

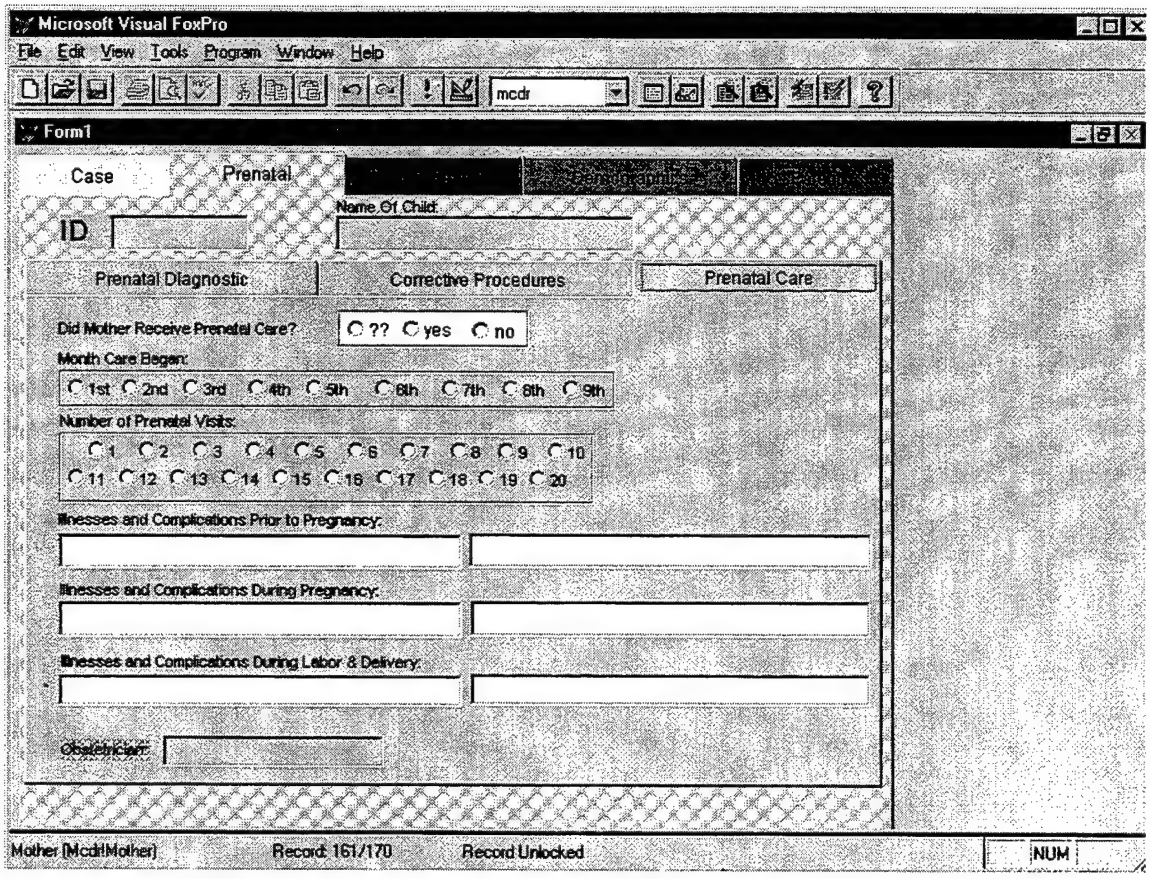

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Birth Data
Reporting Source
Reset
Next
Previous
ADD
Exit
Process
First Name:
Middle Name:
Last Name:
Weight: (grms)
Head Size: (cm)
Length: (cm)
Apgar1:
Apgar5:
Type:
Single
twin
triplet
Sex of each Child:
male
female
other
Gestation Estimated:
EDC:
LMP:
Gestation Actual:
Actual D.O.B.
Gest. Age: (wks, days)
Delivery:
vaginal
cesarean
Pediatrician:
Ph:
Mult. Birth Con.
normal
same def.
other def.
not stated
Case (Mod!Case)
Record: EOF/168
Record Unlocked
NUM

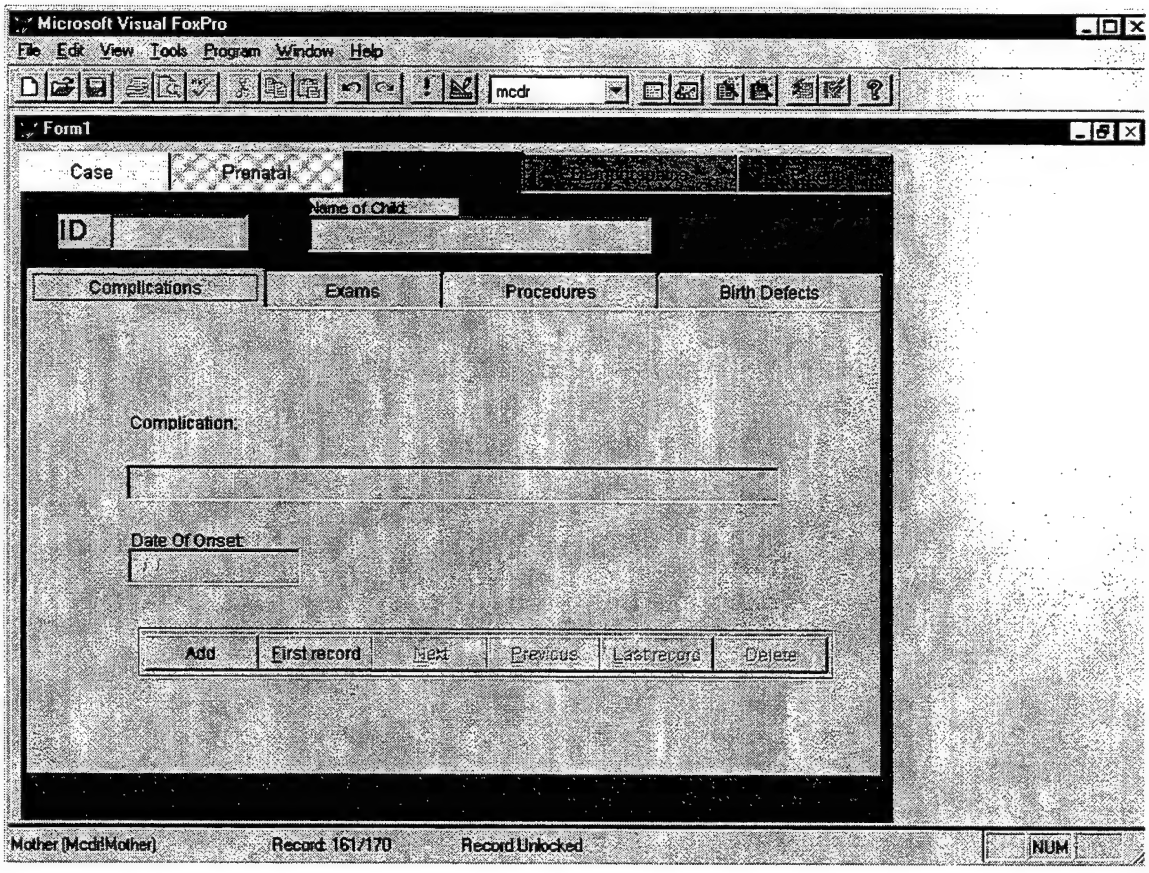

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Birth Data
Reporting Source
live birth
stillbirth
spont.
induced
unspecified
clinic
hospital
home
yes
no
No find
NUM

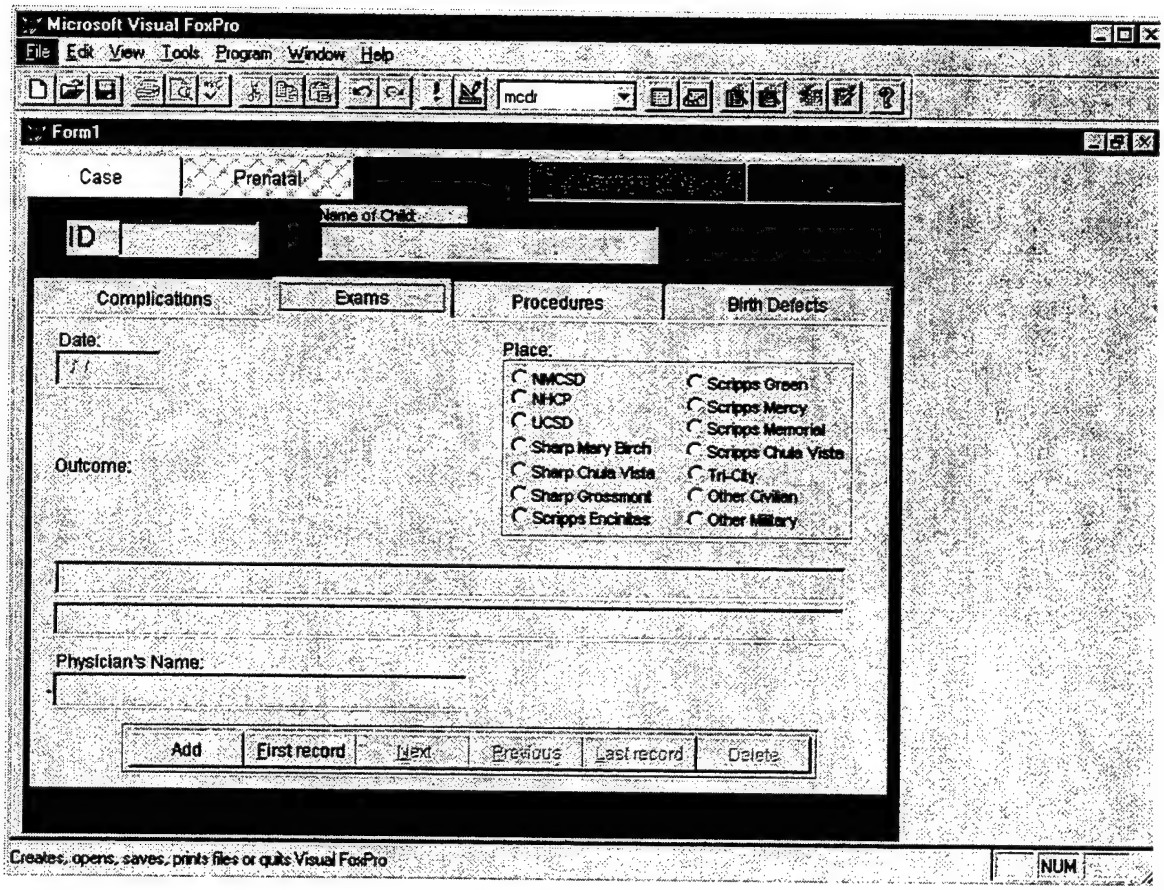

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Birth Data
Reporting Source
First Name:
MI:
Last Name:
Reporting Source:
memo
Case (Mcd!Case)
Record: EOF/168
Record Unlocked
NUM

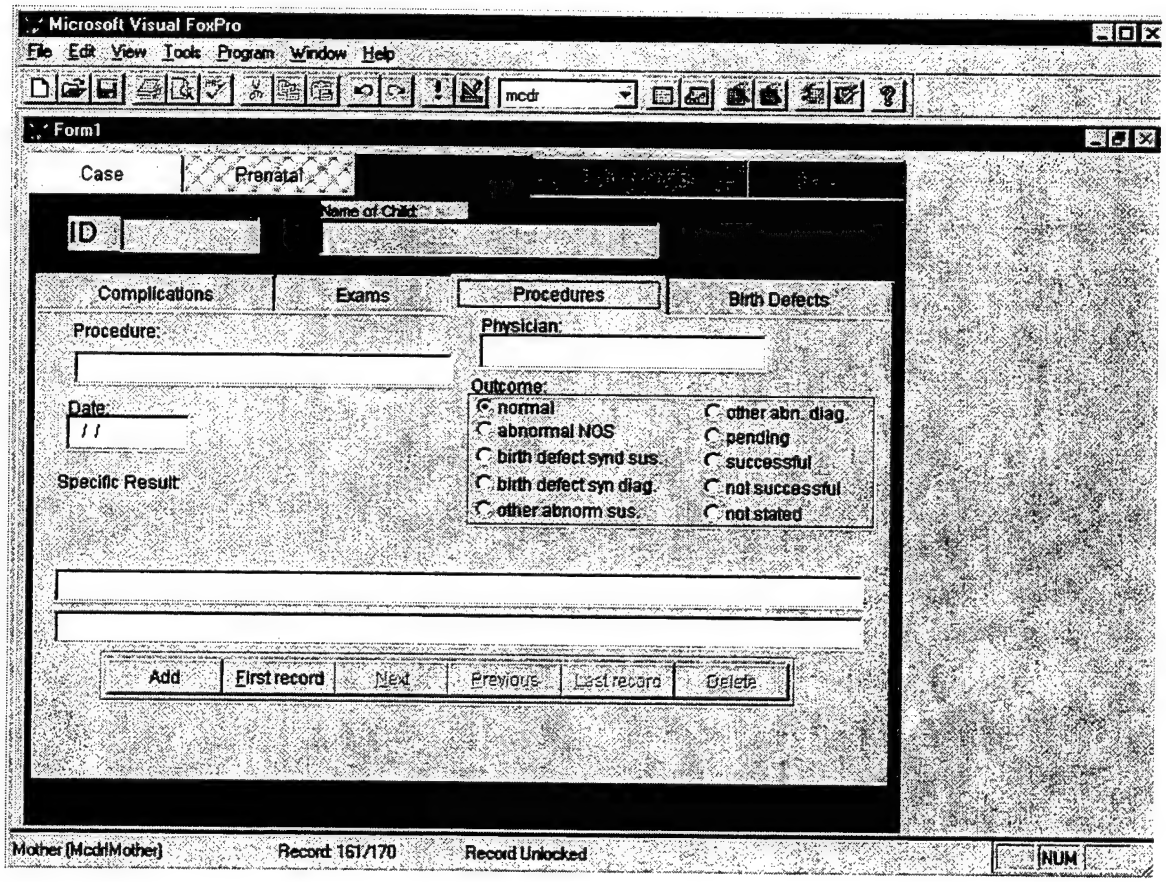

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
ID
Name Of Child
Prenatal Diagnostic
Corrective Procedures
Prenatal Care
Prenatal Index:
Purpose:
Date:
/ /
Outcome:
normal
abnormal NOS
birth defect synd sus.
birth defect syn diag.
other abnorm sus.
other abn. diag.
pending
not stated
Place:
NMCSD
NHCP
UCSD
Sharp Mary Birch
Sharp Chula Vista
Sharp Grossmont
Scripps Encinitas
Scripps Green
Scripps Mercy
Scripps Memorial
Scripps Chula Vista
Tri-City
Other Civilian
Other Military
Specific Results:
Add
First record
Next
Previous
Last record
Delete
Mother (Mcdr!Mother)
Record: 161/170
Record Unlocked
NUM

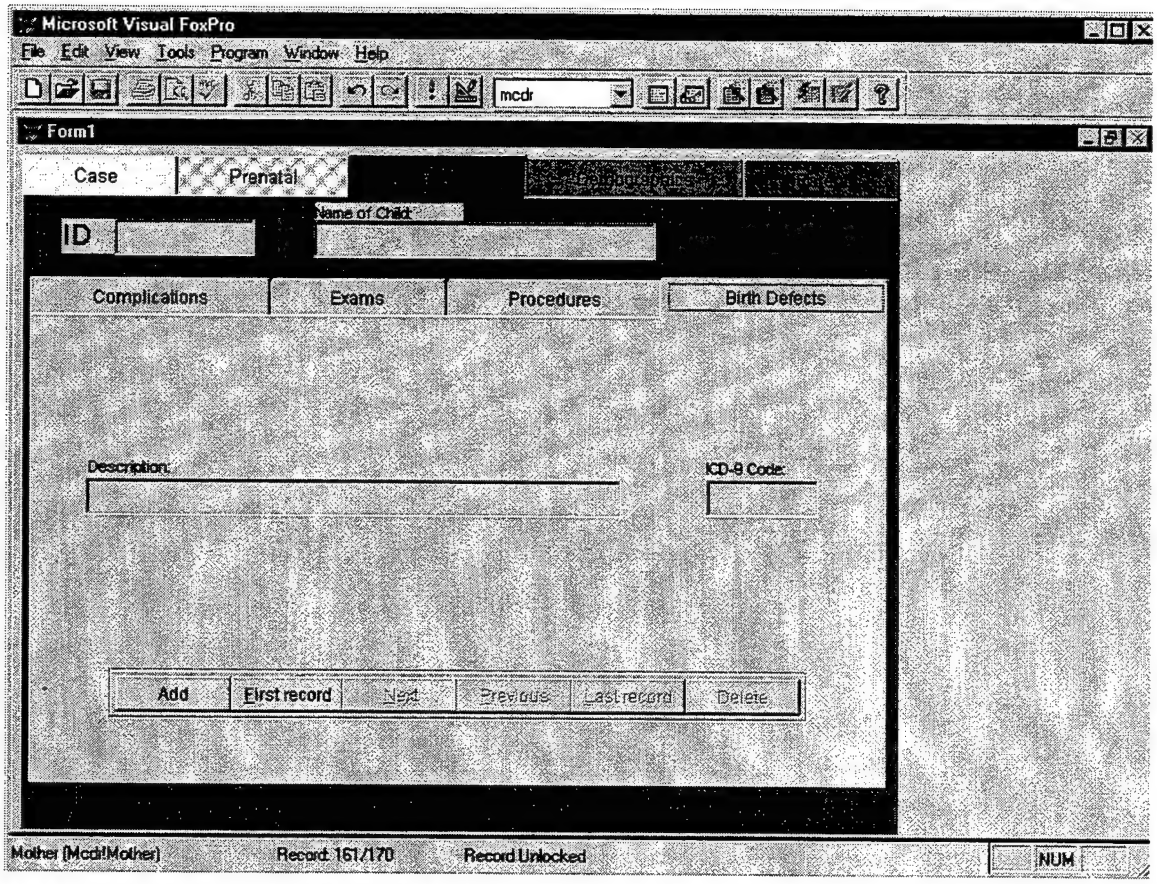

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
ID
Name Of Child
Prenatal Diagnostic
Corrective Procedures
Prenatal Care
Test:
Date:
/ /
Trimester:
1st
2nd
3rd
Prior to Pregnancy
Not Specified
Results:
Add
First record
Next
Previous
Last record
Delete
Mother (Mcdr!Mother)
Record: 161/170
Record Unlocked
NUM

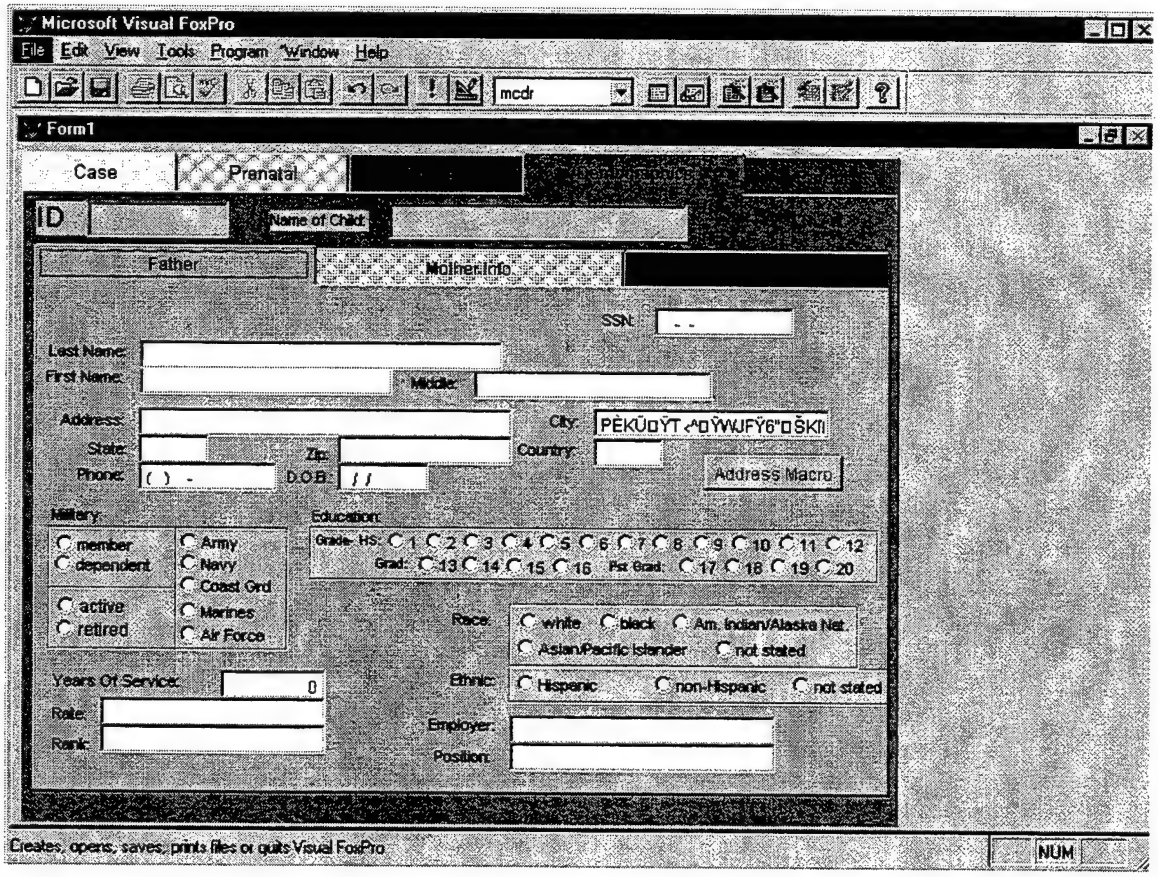

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Name Of Child:
ID
Prenatal Diagnostic
Corrective Procedures
Prenatal Care
Did Mother Receive Prenatal Care?
?? yes no
Month Care Began:
1st 2nd 3rd 4th 5th 6th 7th 8th 9th
Number of Prenatal Visits:
1 2 3 4 5 6 7 8 9 10
11 12 13 14 15 16 17 18 19 20
Illnesses and Complications Prior to Pregnancy:
Illnesses and Complications During Pregnancy:
Illnesses and Complications During Labor & Delivery:
Obstetrician:
Mother (Mcdr!Mother)
Record 161/170
Record Unlocked
NUM

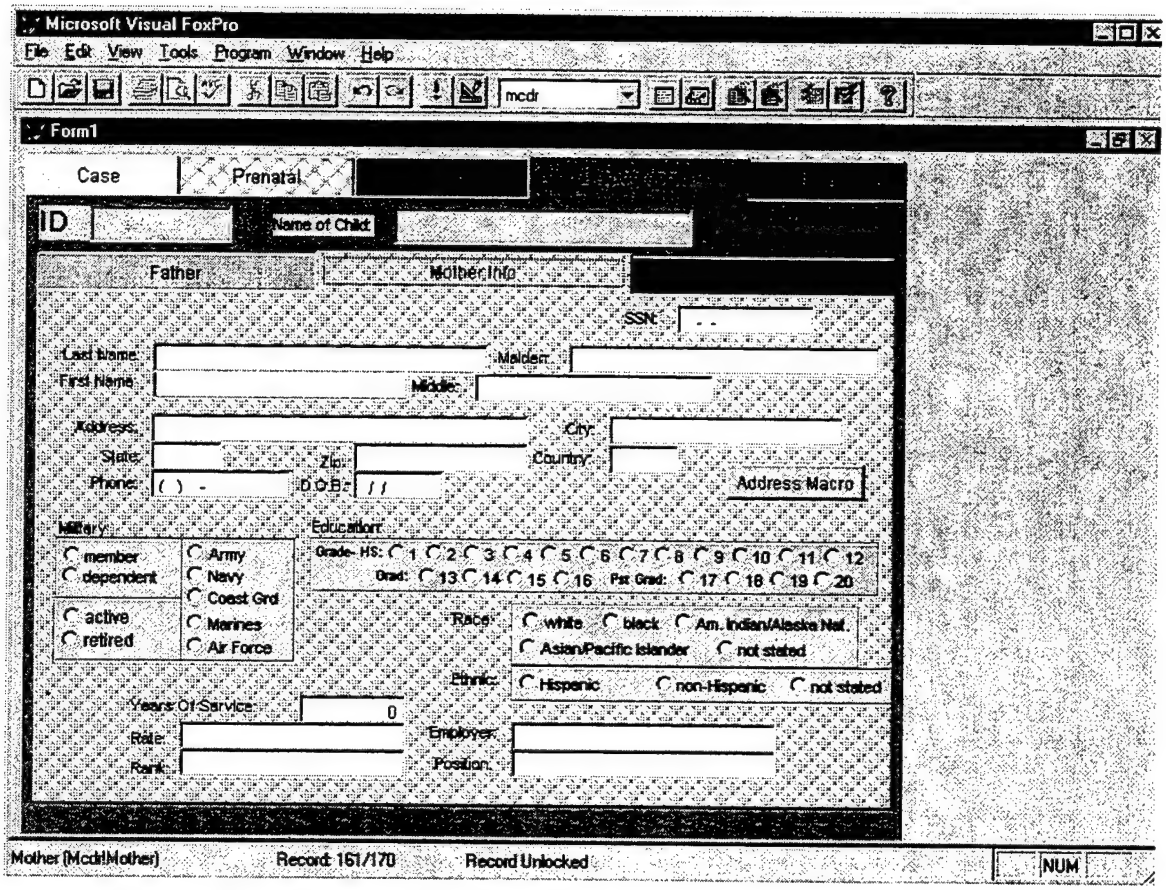

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Name of Child:
ID
Complications
Exams
Procedures
Birth Defects
Complication:
Date Of Onset:
Add
First record
Next
Previous
Last record
Delete
Mother (Mcdr!Mother)
Record 161/170
Record Unlocked
NUM

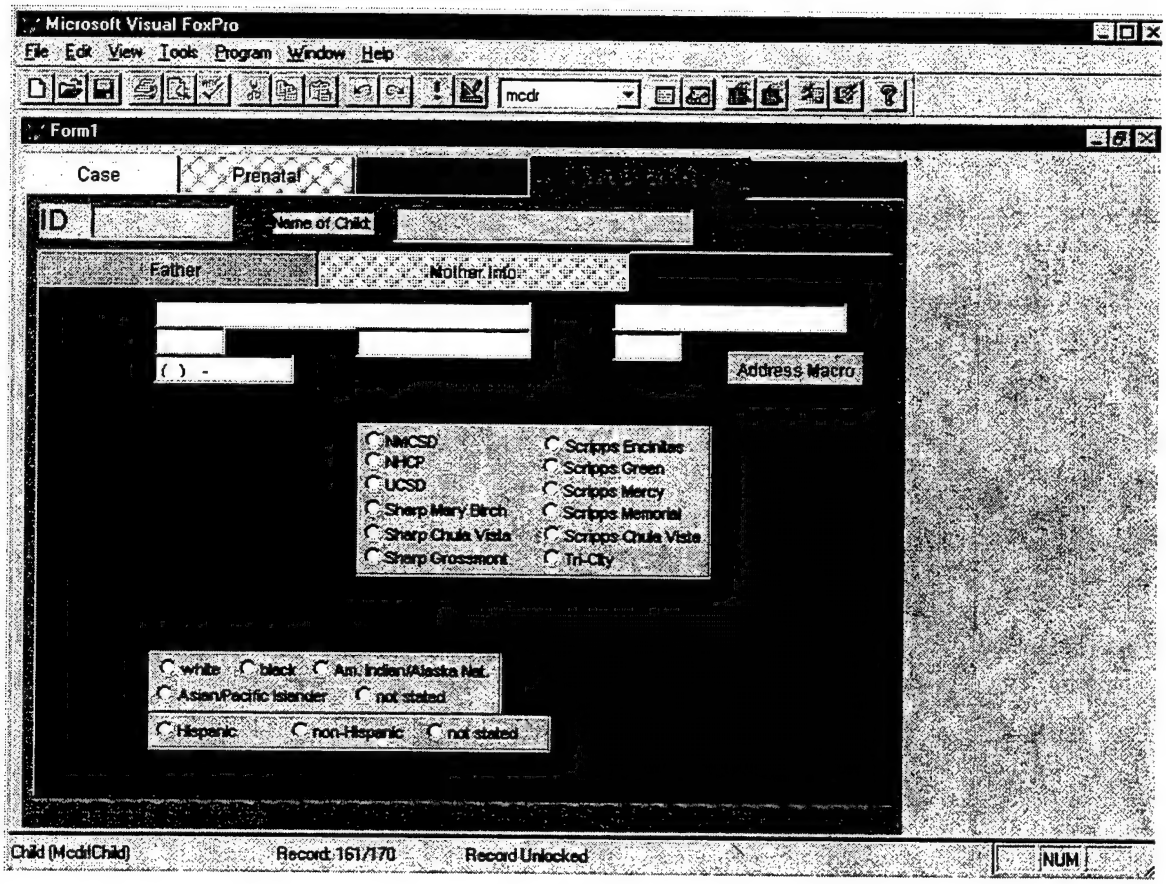

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
ID
Name of Child:
Complications
Exams
Procedures
Birth Defects
Date:
Place:
NMCSD
NHCP
UCSD
Sharp Mary Birch
Sharp Chula Vista
Sharp Grossmont
Scripps Encinitas
Scripps Green
Scripps Mercy
Scripps Memorial
Scripps Chula Vista
Tri-City
Other Civilian
Other Military
Outcome:
Physician's Name:
Add
First record
Next
Previous
Last record
Delete
Creates, opens, saves, prints files or quits Visual FoxPro
NUM

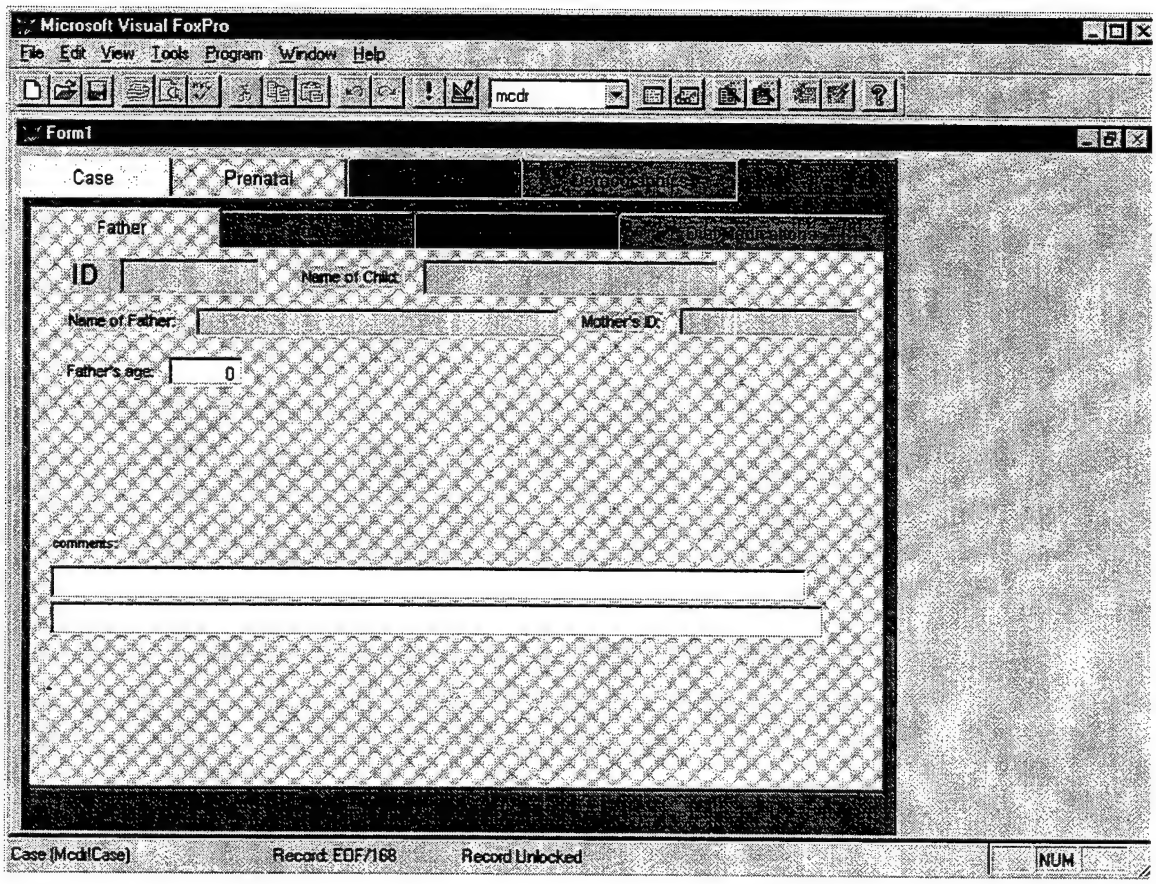

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
ID
Name of Child:
Complications
Exams
Procedures
Birth Defects
Procedure:
Physician:
Outcome:
Date:
normal
abnormal NOS
birth defect synd sus
birth defect syn diag
other abnorm sus.
other abn. diag.
pending
successful
not successful
not stated
Specific Result:
Add
First record
Next
Previous
Last record
Delete
Mother (McdrMother)
Record: 161/170
Record Unlocked
NUM

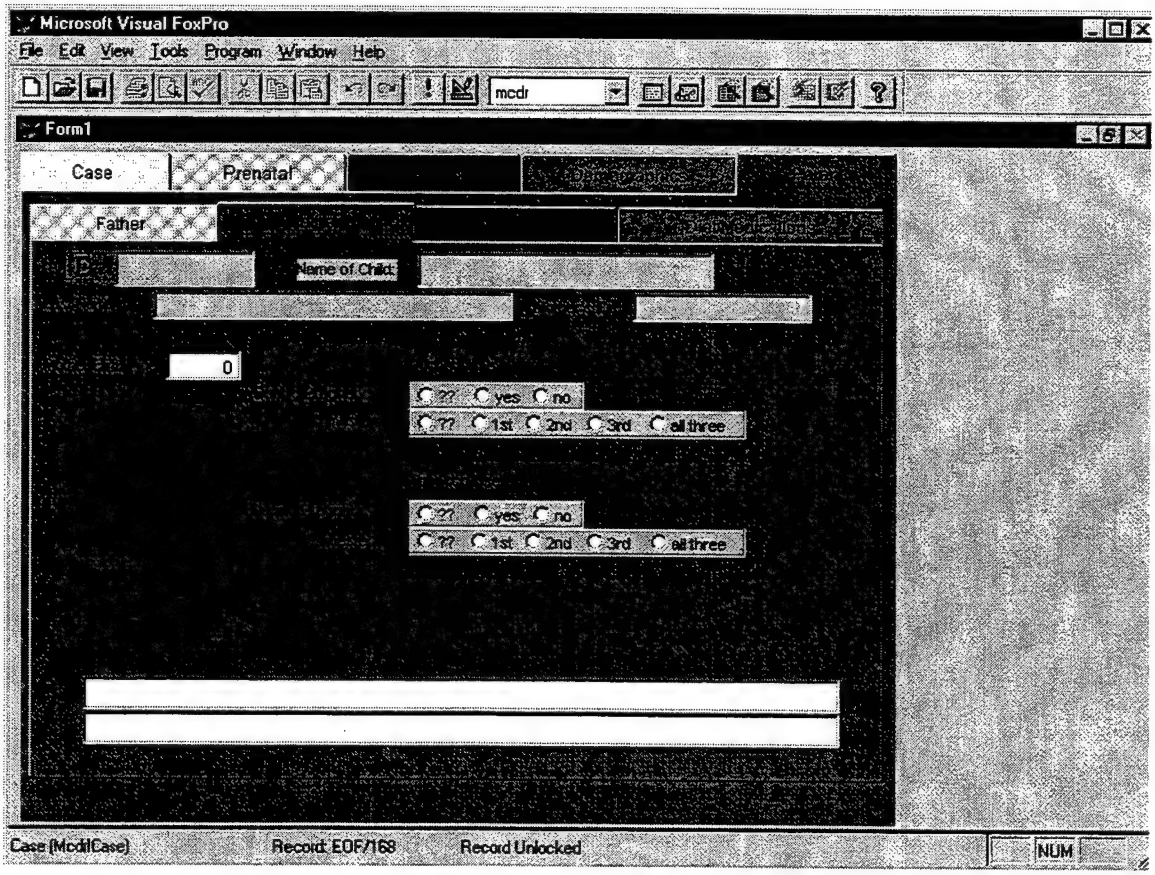

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
ID
Name of Child:
Complications
Exams
Procedures
Birth Defects
Description:
ICD-9 Code:
Add
First record
Next
Previous
Last record
Delete
Mother (Mcd!Mother)
Record 161/170
Record Unlocked
NUM

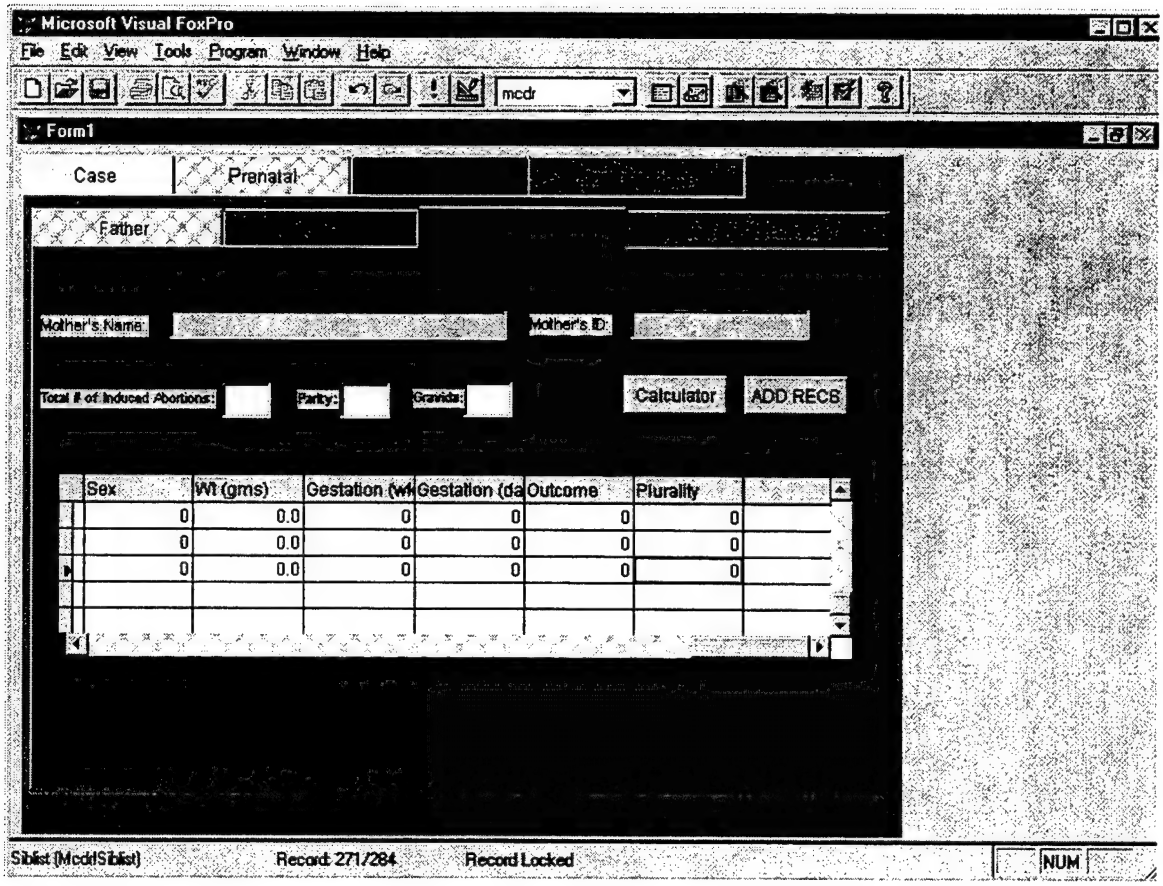

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
ID
Name of Child:
Father
Mother Info
SSN:
Last Name:
First Name:
Middle:
Address:
City:
State:
Zip:
Country:
Phone:
D.O.B:
Address Macro
Military:
member
dependent
Army
Navy
Coast Grd
Marines
Air Force
active
retired
Education:
Grade: HS: 1 2 3 4 5 6 7 8 9 10 11 12
Grad: 13 14 15 16 Pst Grad: 17 18 19 20
Race:
white
black
Am. Indian/Alaska Nat.
Asian/Pacific Islander
not stated
Years Of Service:
0
Rate:
Rank:
Ethnic:
Hispanic
non-Hispanic
not stated
Employer:
Position:
Creates, opens, saves, prints files or quits Visual FoxPro
NUM

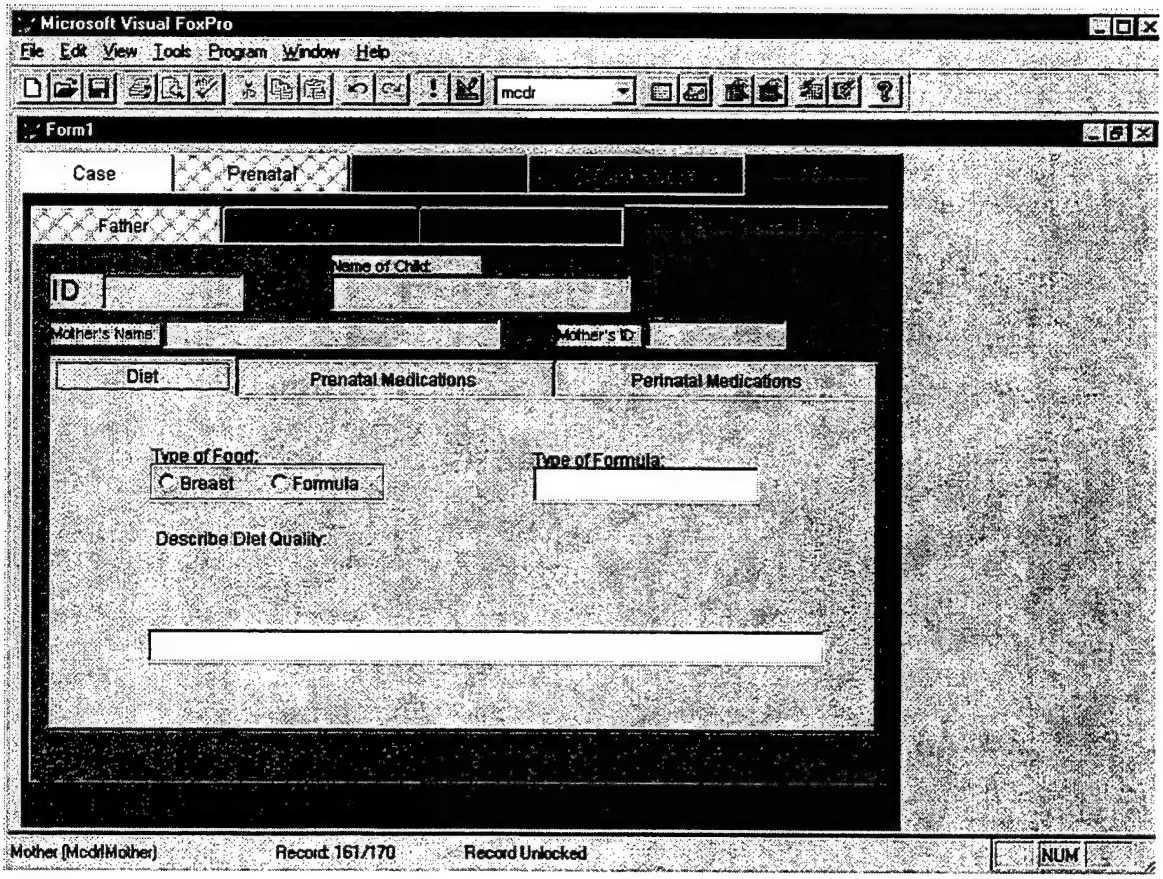

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
ID
Name of Child:
Father
Mother Info
SSN:
Last Name:
Maiden:
First Name:
Middle:
Address:
City:
State:
Zip:
Country:
Phone:
( ) -
D.O.B:
/ /
Address Macro
Military
member
dependent
Army
Navy
Coast Grd
active
retired
Marines
Air Force
Education
Grade- HS: 1 2 3 4 5 6 7 8 9 10 11 12
Grad: 13 14 15 16 Pst Grad: 17 18 19 20
Race:
white
black
Am. Indian/Alaska Nat.
Asian/Pacific Islander
not stated
Ethnic:
Hispanic
non-Hispanic
not stated
Years Of Service:
0
Rate:
Rank:
Employer:
Position:
Mother (Mcdr!Mother)
Record: 161/170
Record Unlocked
NUM

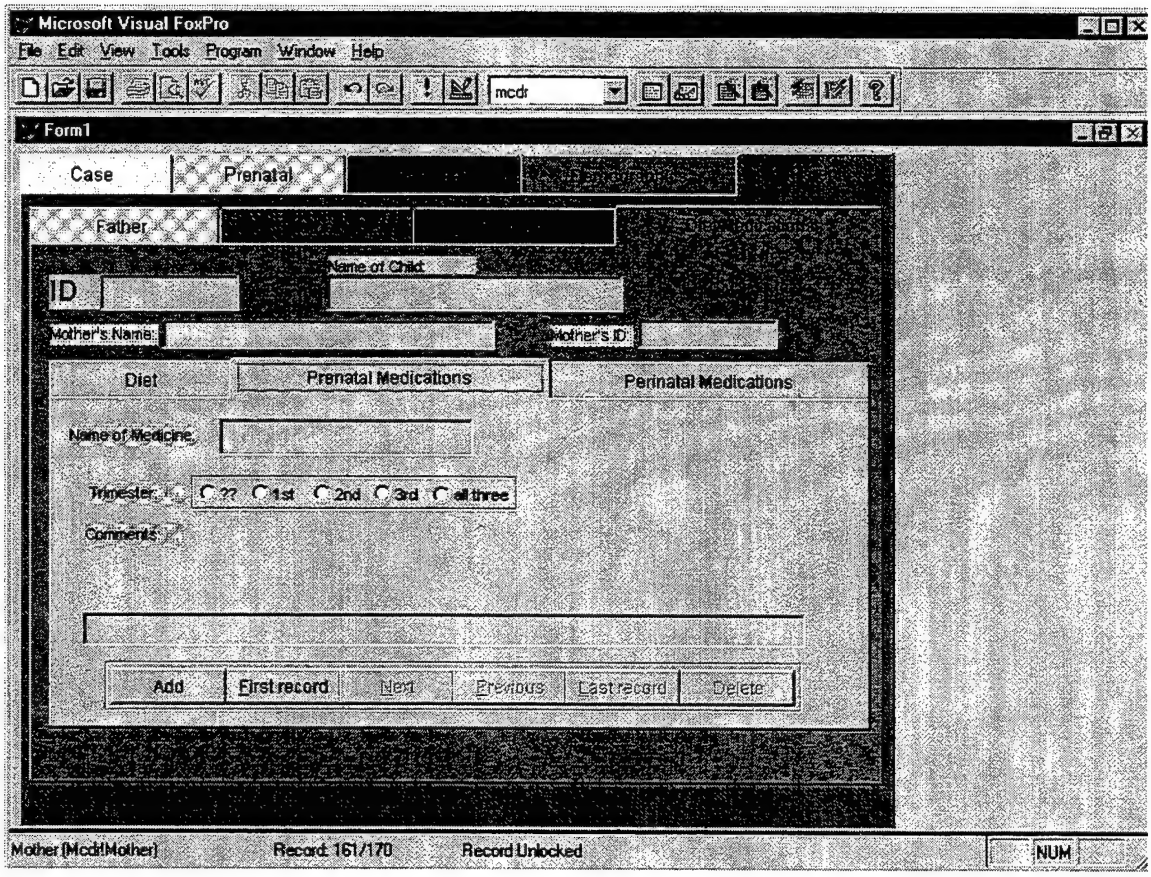

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
ID
Name of Child:
Father
Mother Info
( ) -
Address Macro
NMCSD
NHCP
UCSD
Sharp Mary Birch
Sharp Chula Vista
Sharp Grossmont
Scripps Encinitas
Scripps Green
Scripps Mercy
Scripps Memorial
Scripps Chula Vista
Tri-City
white
black
Am. Indian/Alaska Nat.
Asian/Pacific Islander
not stated
Hispanic
non-Hispanic
not stated
Child (Mcdr!Child)
Record: 161/170
Record Unlocked
NUM

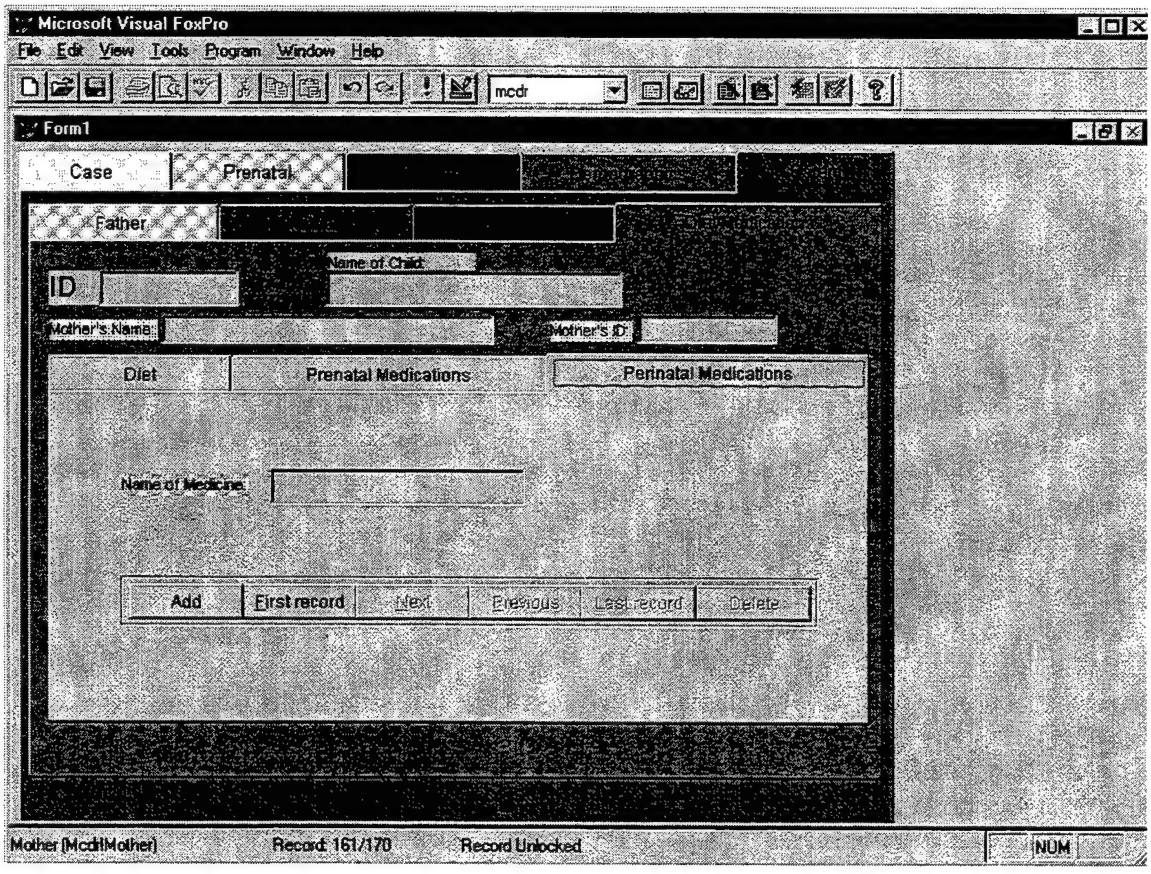

Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Father
ID
Name of Child:
Name of Father:
Mother's ID:
Father's age:
0
comments:
Case (Mcdl!Case)
Record: EOF/168
Record Unlocked
NUM


Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Father
Name of Child:
0
?? yes no
?? 1st 2nd 3rd all three
?? yes no
?? 1st 2nd 3rd all three
Case (Mcdl!Case)
Record: EOF/168
Record Unlocked
NUM


Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Father
Mother's Name:
Mother's ID:
Total # of Induced Abortions:
Parity:
Gravida:
Calculator
ADD RECS
Sex
Wt (gms)
Gestation (wk
Gestation (da
Outcome
Plurality
Siblist (Mcd!Siblist)
Record: 271/284
Record Locked
NUM


Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Father
ID
Name of Child:
Mother's Name:
Mother's ID:
Diet
Prenatal Medications
Perinatal Medications
Type of Food:
Breast
Formula
Type of Formula:
Describe Diet Quality:
Mother (Mcd!Mother)
Record: 161/170
Record Unlocked
NUM


Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Father
Name of Child:
ID
Mother's Name:
Mother's ID:
Diet
Prenatal Medications
Perinatal Medications
Name of Medicine:
Trimester:
?? 1st 2nd 3rd all three
Comments:
Add
First record
Next
Previous
Last record
Delete
Mother (Mcdr!Mother)
Record: 161/170
Record Unlocked
NUM


Microsoft Visual FoxPro
File Edit View Tools Program Window Help
mcdr
Form1
Case
Prenatal
Father
Name of Child:
ID
Mother's Name:
Mother's ID:
Diet
Prenatal Medications
Perinatal Medications
Name of Medicine:
Add
First record
Next
Previous
Last record
Delete
Mother (Mcdr!Mother)
Record: 161/170
Record Unlocked
NUM

Appendix E

Passive Surveillance Notification Postcard

In order to identify military dependents born with birth defects, the **Military Congenital Defects Registry Pilot Study** would appreciate the time taken to fill out this preliminary screening survey. Please give as much of the information as possible. This study will contribute to identification of congenital anomalies in the military community. Thank you, BDR Researchers.	HOSPITAL/CLINIC:_____ _____ ❑ NICU ❑ LABOR AND DELIVERY ❑ PICU ❑ Fetal Assessment Unit ❑ Pediatric clinic ❑ OB-GYN clinic ❑ OTHER:_____ _____
PATIENT INFORMATION: ☐ Mother ☐ Child	**FETAL ASSESSMENT ONLY** Two or more **positive** prenatal screening test? Y or N ☐ Ultrasound ☐ Amniocentesis ☐ Other

DEMISE	**COMMENTS**
Did this child die? ❑ Yes ❑ No If yes was an autopsy Ordered? ❑ Yes ❑ No	_____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Primary Systems Disturbed by Defects: (Specific Diagnosis Optional)				
❑ Central Nervous System (CNS)	❑ Circulatory System	❑ Cleft palate/lip	❑ Digestive	❑ Respiratory
❑ Ears, Eyes, Face, and Neck	❑ Genitourinary System	❑ Musculoskeletal Deformities	❑ Chromosomal Anomalies	❑ Other (specify if possible)

Appendix F

Memorandum of Understanding
Between
Commander, Naval Health Research Center
and
Corporate Executive Information System
Customer Service Division

26 March, 1998

MEMORANDUM OF UNDERSTANDING
BETWEEN
COMMANDER, NAVAL HEALTH RESEARCH CENTER
AND
CORPORATE EXECUTIVE INFORMATION SYSTEM
CUSTOMER SERVICE DIVISION

Subject: MEMORANDUM OF UNDERSTANDING

Reference: DATA REQUEST DATED 11 FEBRUARY 1998

1. Purpose. This document provides an understanding between the Naval Health Research Center and the Corporate Executive Information System (CEIS) Customer Service Division (CSD) concerning data to be furnished to the Naval Health Research Center by the Analysis Branch of the CEIS Customer Service Division.

a. Facts. The Corporate Executive Information System Customer Service Division was initially contacted on 29 January 1998 by Susan Hilton of the Naval Health Research Center requesting assistance in providing data for birth defect surveillance among selected US military health care beneficiaries residing in San Diego County, CA.
Ms. Hilton indicated that the request for data was to supplement data previously requested from the Defense Manpower Data Center (DMDC). The data was being requested from CEIS CSD because DMDC could only provide Military Medical Treatment Facility data for a portion of the required time frame in the request.

b. Intentions. The Corporate Executive Information System Customer Service Division will enter into an agreement with the Naval Health Research Center to provide direct care inpatient data and DEERS data requested by the Naval Health Research Center in a written data request dated 11 February 1998.

c. Coordination. Coordination between the Naval Health Research Center and the Corporate Executive Information System is being conducted by Susan Hilton from the Naval Health Research Center and Terri Amrhein from the Corporate Executive Information System Customer Service Division/Patient Administration Systems and Biostatistics Activity (PASBA), Fort Sam Houston, TX.

d. Limitations. Funds for the cost of the project must be provided via Military Interdepartmental Purchase Request(MIPR) prior to release of the data.

Subj: MEMORANDUM OF UNDERSTANDING

2. Problem. After research, the CEIS CSD does not have access to inpatient and outpatient records of CHAMPUS claims data. The Naval Health Research Center should request this data from: Ms. Sieleen Mullen
Director, Acquisition and Management
OCHAMPUS
Aurora, CO 80045

3. Scope. The Corporate Executive Information System Customer Service Division will provide records agreed upon by the Corporate Executive Information System Customer Service Division and the Naval Health Research Center. The cost of the project will not exceed **$5,000.00**. The actual cost of the project will be provided to the Naval Health Research Center upon completion of work. The estimated date of completion of the project is **8 May 1998**. The CEIS CSD will notify the Naval Health Research Center if problems are encountered.

4. Agreement/Understanding. The Corporate Executive Information System Customer Service Division will furnish direct care inpatient data as requested in the 11 February 1998 data request from CAPT Gregory Gray (attached) for the following diagnosis codes: 630 through 677, 740-759, V27, V3, 228, 259, 352, 331, 560, 760-798. The data will be for active duty Navy and Marine Corps sponsors and their dependents for 91900 through 92199 zip codes of residence (87 total) in San Diego County, CA, who were discharged from Army, Navy, or Air Force inpatient medical treatment facilities during October 1994 through September 1997.

The Corporate Executive Information System Customer Service Division will also provide DEERS data for October 1994 through September 1997 for active duty Navy and Marine Corps sponsors and their dependents for 91900 through 92199 zip codes in San Diego County, CA.

5. Effective Date. This Memorandum of Understanding will take effect **27 March 1998**.

27Mar98

LARRY M. DEAN
CAPT, MSC, USN
Commanding Officer
Naval Health Research Center

CARL E. HENDRICKS
LTC, USA
Chief, CEIS Customer
Service Division/PASBA

CF: Ms. Barbara S. Morris
Budget Analyst, CEIS CSD/PASBA, (210) 295-8640

11 February 1998

DATA REQUEST: 3 PAGES

From: CAPT Gregory C. Gray, MC, USN, Emerging Illness Division, Naval Health Research Center, San Diego, CA 92186-5122, TEL 619 553-9967, FAX 619 553-7601

To: Mr. Larry Humphrey, Corporate Executive Information Systems, Customer Support Division, Patient Administration Systems & Biostatistics Activity, 1216 Stanley Road, Fort Sam Houston, TX 78234, TEL (210) 221-0688, DSN 471-0688, FAX (210) 221-2046, DSN 471-2046

CC: Susan Hilton, James Knoke, Ruth Bush, Gil Fries

Ref: (a) PhonCons of 29-30Jan98 between Susan Hilton (NHRC) and Gil Fries (CEIS); Ticket Number 9801MED03969.

Subj: DATA NEEDED FOR EPIDEMIOLOGICAL RESEARCH ON MILITARY BENEFICIARIES

1. We are conducting birth defect surveillance among US military health care beneficiaries in San Diego County, and need to know how many births took place and will take place among active duty Navy and Marine Corps personnel from October 01, 1994 through June 30, 1998 in San Diego County, and how many births involved birth defects. To do this, we have requested three data extractions from Defense Manpower Data Center (DMDC): (a) DoD hospitalization data for military sponsors and dependents in San Diego County between October 01, 1994 and July 01, 1998, (b) inpatient and outpatient records of CHAMPUS claims in San Diego County between October 01, 1994 and July 01, 1998, and (c) all new dependent enrollments in DEERS in San Diego County between October 01, 1994 and July 01, 1998, as well as sponsor and joint spouse data associated with those dependents. However, DMDC does not have DoD hospitalization data beyond 1995. We have been referred to you as the source for the data not available from DMDC. To avoid format inconsistencies and data incompatibilities between data sets, we would like to acquire the full datasets, as available, from your command. Therefore, we request your assistance in obtaining the data extractions described below as discussed in reference (a). The data requested do contain Privacy Act information.

   a) Dataset I:

   Data Source, Selection Frame, & Selection Set: Direct Care Inpatient data for FY95 through latest available date (December 30, 1997?) for active duty Navy and Marine Corps sponsors and dependents in San Diego County (zipcodes 91900 through 92199).

   Variables: (variable names assume "Patient" is the mother, "Beneficiary" is the newborn, and "Sponsor" is the mother or father)

Admission Date
Admission Source
Beneficiary Birth Date
Beneficiary Category
Beneficiary Gender
Beneficiary Name
Beneficiary Race
Diagnoses (first eight ICD-9 codes)
Disposition Date
Disposition Type
DMIS Identifier of Reporting Facility (HCI)
Family Member Prefix
Newborn Identification
Patient Birth Date
Patient Category
Patient Gender
Patient Marital Status
Patient Name
Patient Occupation
Patient Paygrade
Patient Race
Patient Residential Zipcode
Patient Social Security Number
Residence Location
Sponsor Birth Date
Sponsor Gender
Sponsor Marital Status
Sponsor Name
Sponsor Occupation
Sponsor Paygrade
Sponsor Race
Sponsor Service Branch
Sponsor Social Security Number

b) Dataset II:

Data Source, Selection Frame, & Selection Set: Inpatient and outpatient records of CHAMPUS claims data for FY95 through latest date currently available for active duty Navy and Marine Corps in San Diego County (zipcodes 91900 through 92199).

Variables: same as Dataset I.

c) Dataset III:

Data Source, Selection Frame, & Selection Set: All new dependent enrollments in DEERS for FY95 through latest date currently available for active duty Navy and Marine Corps in San Diego County (zipcodes 91900 through 92199), as well as some Sponsor and Joint Spouse data associated with those dependents.

Variables:

Age of Dependent/Sponsor
Coordinated Care Program
Date of Beginning Eligibility
Date of Ending Eligibility
Date of Birth of Dependent/Sponsor
Date of Data, Year
Date of Data, Month
DEERS Dependent Suffix
Disability/Retired Type
DMIS of Enrollment
Duty Status of Sponsor
Eligibility Code
Family Sequence Number
Group Code
Marital Date
Marital Status
Name of Dependent/Sponsor
Number of Dependents Reported
Number of Eligible CHAMPUS Deps.
Number of Eligible Dependents Counted
Occupation
Paygrade
Provider Code
Race of Dependent/Sponsor
Reason for Ending Eligibility
Record Type
Relationship Between Dependent & Sponsor
Reserve Component Category
Residence Address DMIS
Residence Address Hospital Catchment
Residence Address Region
Residence Address State/Country
Residence Address Zip
Sex of Dependent/Sponsor
Social Security Number of Dependent
Social Security Number of Sponsor
Source of Data
Sponsor's Branch of Service
Unit Identification Code
Unit DMIS
Unit Hospital Catchment
Unit Region
Unit State/Country
Unit Zip

2. The product files (ASCII preferred, SAS or raw data is fine) can be received either electronically, on cartridge (38K, single density format, ASCII/EBCDIC), or on 3-1/2" diskette (DOS-formatted). My point of contact is Susan Hilton, telephone (619) 553-7603. Thank you for your assistance.

Sincerely,

Appendix G

CHAMPUS Data Request

DEPARTMENT OF THE NAVY
NAVAL HEALTH RESEARCH CENTER
POST OFFICE BOX 85122
SAN DIEGO, CA 92186-5122

IN REPLY REFER TO:
6500
Ser 232/433
December 2, 1997

Fred Hammer
Chief of Information Systems
Building 223
OCHAMPUS
Aurora, CO 80045

Dear Mr. Hammer:

We request your assistance in obtaining the necessary data to assist our research team at Naval Health Research Center in San Diego in a pilot study to determine the feasibility of conducting national Department of Defense surveillance for birth defects among military populations. Beginning such a surveillance project is of great importance to the health of military personnel and their families and is advocated by the Department of Defense, Health Affairs (see enclosed letter 1).

One of the challenges in conducting such surveillance is to capture information about the births and the birth defects identified during the first year of life among military beneficiaries who used civilian medical facilities. In order to gather this information, we request your assistance for the data extraction described below.

Selection Criteria:

We are focusing on specific ICD-9 and V codes that represent congenital anomalies which indicate that a pregnancy was not carried to term, or indicate that a multiple birth took place (see enclosed list 2). We are interested in all cases that meet these criteria, whether a primary diagnosis or one of the numerous secondary diagnoses. In terms of time parameters, we are interested in cases that are identified as part of prenatal care (and are part of the maternal health record), at birth, and as part of outpatient care for children through one year of age.

Specifically, we would like the following data for all San Diego Country beneficiaries for the period FY 95 through FY 97, as well as on a periodic basis (for example monthly) as the data become available for FY 98.

Desired Variables:

Sponsor Social Security Number
Sponsor Pay Grade
Sponsor Branch of Service [we are interested in Navy and Marine Corps personnel only]
Sponsor Status
Patient Relationship to Sponsor
Patient Name
Patient SSN

Desired Variables (con't):

Patient Date of Birth
DEERS Dependent Suffix
Patient Sex
Patient Zip Code
Enrollment Status
NAS Exception Reason
Provider Name
Provider Zip Code
Principal Treatment Diagnosis
Secondary Treatment Diagnosis -1
Secondary Treatment Diagnosis -2
Secondary Treatment Diagnosis -3
Secondary Treatment Diagnosis -4
Secondary Treatment Diagnosis -5
Secondary Treatment Diagnosis -6
Secondary Treatment Diagnosis -7
Secondary Treatment Diagnosis -8
Military Treatment Facility
Patient Age
Race/Ethnicity
Source of Health Care Data
Type of Institution or Provider's Major Specialty

Ideally, this information would be provided in an ASCII format, with a description of the field structure. We would be glad to send a zip drive tape if that would facilitate the exchange.

Please let us know if we can provide any further clarification so as to facilitate this request. My point of contact for this matter is Ms. Ruth Bush, telephone (619) 553-9017, fax (619) 553-7601.

Very Sincerely,

G. C. Gray
CAPT MC USN
By direction of the
Commanding Officer

Enclosures:
1. Off. of the Asst. Sec. of Def. ltr of 21 Oct 97
2. MCDR PILOT ICD-9 CODES CASE FINDING INCLUSION LIST

Appendix H

Committee for the Protection
of Human Subjects
Correspondence

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS' RECOMMENDATION

Date of Review: November 20. 1997 Protocol Number: 31248

Dates of the Research: 971101–981030

Title of Research Protocol: Pilot Study—Surveillance for Birth Defects Among US Naval Health Care Beneficiaries in San Diego County

Principal Investigator: G. Gray

Work Unit Number: 61102A.M0101.BKX-6609

In its review, the Committee was unable to determine whether the research and safeguards described in the attached research protocol met the standards set forth in DoD directive 3216.2, SECNAVIST 3900.39B, NMRDCINST 3900.2, and any locally applicable instructions. Those instructions require limiting the participation of humans as experimental research volunteers to those situations in which voluntary informed consent is obtained. Such participation also must be confined to research projects and clinical investigations that are necessary, scientifically sound, reasonably safe, and in which the benefit to be derived clearly justifies the risk incurred by the research volunteer. Minutes of our deliberations concerning the review of this research protocol are attached, including anonymous statements giving reason(s) for nonconcurrence or abstention (if the recommendation of the committee is not unanimous).

Minutes and recommendations of the meeting of November 20, 1997:

The Committee discussed this protocol for birth defects surveillance at length. Significant questions need to be answered before the Committee can rule on this protocol. First, some Committee members believed other investigators have conducted similar research. The protocol should be revised to clarify the specific need that will be filled by this study. Second, personal identifiers will be collected, so the study is not exempt. The consensus was that the protocol probably could be approved as minimal risk if informed consent were obtained from the participants. It was recognized that this consent requirement could significantly increase the resources required to conduct the study, thereby making it impractical or impossible to complete the study as planned. For this reason, it might be appropriate to consider requesting a waiver of informed consent. Under the guidelines in the existing CPHS instructions, several conditions must be satisfied to grant a waiver. Two key conditions are that it must be shown that the study is not practicable without such a waiver and that granting a waiver will not adversely affect the study participants. The Committee also wanted to know whether the requisite information could be obtained from medical records of the mother. If so, mothers who are Navy personnel have signed a Privacy Act statement providing for the use of their medical data for research purposes. It should be determined whether a similar statement is signed by dependents receiving care in Navy hospitals and under the CHAMPUS program.

The discussion raised a number of concerns that could not be resolved on the basis of information available to the Committee at the time of the meeting. These concerns can be resolved only after CPHS guidelines and legal issues have been clarified. For this reason, the Committee was unable to provide specific

guidance regarding modifications that were required, if any, to make the protocol acceptable. CPHS guidelines require specific guidance, so the Chair will seek additional information on these issues prior to the next CPHS meeting, December 11. Further discussion o f the protocol was tabled until that time. Please have a project representative prepared to attend that meeting to assist in resolving these issues.

Ross R. Vickers, Jr., Ph.D.
Chair, NHRC CPHS

2-Dec 97
Signature & Date

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS RECOMMENDATION
INITIAL REVIEW

Date of Review: 6 Feb 98 Protocol Number: 31248

Title of Research Project: Pilot Study - Surveillance for Birth Defects Among U.S. Naval Health Care Beneficiaries in San Diego County

Principal Investigator: G. C. Gray

Work Unit Number: 61102A M0101.BKX-6609

Proposed Dates of Research: 1 Nov 97 - 31 Oct 98

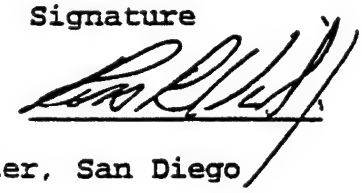
Background. This protocol originally was reviewed by the CPHS on 20 Nov 97. At that time, CPHS saw a need for special care in the collection and management of the data given the sensitivity of information about birth defects. This concern was addressed in revision of the protocol that incorporated strict data access controls used successfully in California's Birth Defects Registry. CPHS also was concerned about the planned extraction of individual identifiers from children's health records. Linking identifiers to sensitive health information raised issues about the balance between the individual's right to privacy and the need for support of Navy health policies. The balance seemed particularly delicate given that children's health records were being reviewed. Third party consent would be required to involve children in a research project. The first step in resolving this second concern was the determination that 10 USC 980, a section of the federal code that might have prohibited third party consent, was not applicable. 10 USC 980 applies to experimental studies; the present study is nonexperimental. The issue, therefore, was reduced to how to best obtain the required consent. A determination was made that the standard Privacy Act Statement provides acceptable evidence of informed consent for the present purposes. The Privacy Act Statement states that research is one routine use of health records. The Privacy Act Statement also states that signing must be a voluntary act for dependents. The consent provided by the Privacy Act Statement is nonspecific. Past CPHS practice has relied on protocol-specific consent forms that permit subjects to review and approve the specifics of their involvement. This approach was not feasible for this study because the available resources are too limited to track down potential participants and request specific consent. Requiring specific consent would make it impossible to perform the study. In such cases, NMRDCINST 3900.2 provides for the modification or even waiver of elements of informed consent in some cases. CPHS felt that U.S. Navy personnel understood that research use of health records was a possibility when they signed the Privacy Act Statement. Given these considerations, the judgment was that the signed Privacy Act Statement constituted sufficient evidence of informed consent for this protocol.

Recommendation. CPHS recommends that the study be approved as a minimal risk investigation. The recommendation carries two specific conditions. First, procedures developed and successfully implemented by the California Birth Defects Registry to protect against inappropriate disclosure of the data must be followed. These procedures have been incorporated into the protocol at this time. These procedures have been successfully used by the state of

California for an extended period. CPHS believes they provide adequate safeguards for privacy. If any problem arises with respect to protecting the privacy of the data, the investigators are to report that problem to CPHS just as they would report any accident or injury that might occur in other types of protocols. Second, CPHS requires that a signed Privacy Act Statement be present in the health record before any individual identifier information is extracted from the health record. If the Privacy Act Statement is missing from the record or is unsigned, identifier data is not to be taken from the record, but data on the health of the child can be recorded. This anonymous extraction of health data conforms to practices that are exempt from NMRDCINST 3900.2 and related instructions. The intent of this requirement is to permit a full census of birth defects data while limiting risk of inadvertent disclosure of the sensitive health information to cases in which there is documented permission for the records to be reviewed. A waiver of this requirement should be considered if Privacy Act Statements are missing for a high proportion of children or if analysis indicates that records with signed statements are not representative of the general population of births.

Approval Sheet. The points made in the preceding recommendation were agreed to at the most recent CPHS meeting. The accompanying CPHS signature sheet was signed at the meeting. Because the recommendation was more complex than usual, all CPHS members review the specifics of the written recommendation. The objective was to ensure that the elements of approval agreed upon at the CPHS meeting had been accurately incorporated into the recommendation. CPHS concurred that the above recommendation accurately reflects what was discussed and approved at the meeting.

Next scheduled review recommended on or before: 31 Jan 99.

Typed Name, Address & Representation	Signature	Date
Ross R. Vickers, Jr. Chair, CPHS Naval Health Research Center, San Diego		2 FEB 98

****

RECOMMENDATION OF CONVENING AUTHORITY

(1.) I concur with the recommendation of the Committee for the Protection of Human Subjects (CPHS).

2. I concur with the recommendations of the CPHS, but recommend additional modifications or restrictions (Attach recommendations).

3. I disagree with the recommendation of the CPHS and recommend ... (Attach recommendations and reasons).

Typed Name & Title	Signature	Date
Larry M. Dean Commanding Officer	Larry M. Dean	3/23/98

****

DETERMINATION OF THE APPROVING AUTHORITY

(1.) I concur with the recommendation of the CPHS and the Committee Convening Authority, and approve the research for a period of one year from the date below:

Review Required No Later Than: 1/31/99

2. I concur with the recommendation of the CPHS and the Committee Convening Authority, but require the attached additional modifications or restrictions prior to providing approval.

Review Required No Later Than: ___/___/___

3. I disagree with the recommendations of the CPHS or the Committee Convening Authority and make the attached recommendations.

Typed Name & Title	Signature	Date
LARRY M. DEAN COMMANDING OFFICER	Larry M. Dean	3/23/98

Appendix I

Correspondence
From
Naval Medical Center San Diego
Institutional Review Board

DEPARTMENT OF CLINICAL RESEARCH
NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

6500
AVA
9 Feb 98

From: Head, Clinical Investigation Department
To: Deputy Commander

Subj: **MINUTES OF THE SCIENTIFIC REVIEW COMMITTEE, THE LABORATORY ANIMAL CARE AND USE COMMITTEE, AND THE COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS OF 14, 16 AND 20 JANUARY 1998**

Ref: (a) SECNAVINST 3900.38B
(b) SECNAVINST 3900.39B
(c) HSETCINST 6000.41A
(d) BUMEDINST 3900.8
(e) NAVMEDCEN SDIEGOINST 6500.2A
(f) NAVMEDCEN SDIEGOINST 6500.4D
(g) NAVMEDCEN SDIEGOINST 6500.5C
(h) NAVMEDCEN SDIEGOINST 6500.7D
(I) NAVMEDCEN SDIEGOINST 6710.16D
(j) NAVMEDCEN SDIEGOINST 5420.5B

Encl: (1) SRC Attendance Matrix
(2) CPHS Attendance Matrix
(3) LACUC Attendance Matrix

1. The SRC was convened by the Chairman, D. L. Reeves, CDR, MSC, USN, at 1300 hours on 14 January 1998. The LACUC was convened by Chairman M. Keefe, CDR, MC, USN at 0900 on 16 January 1998. The CPHS was convened by Chairman, K. D. Gubler, CDR, MC, USN, at 1330 hours on 20 January 1998. Enclosures (1) through (3) identify committee members in attendance. Invited to present were:

LCDR Hoffer
Otolaryngology Department

CDR Mull
Critical Care Department

LCDR Ross
Dermatology Department

LT Kacere
Cardiology Division

CDR Wandel
Plastic Surgery

CDR Sageman
Pulmonary Department

CAPT Gray
NHRC

CAPT Millard
Hem/Onc Division

DEPARTMENT OF THE NAVY
NAVAL MEDICAL CENTER
34800 BOB WILSON DR.
SAN DIEGO, CALIFORNIA 92134-5000

IN REPLY REFER TO:
6500
AVA
23 Feb 98

From: Commander, Naval Medical Center, San Diego
To: Commanding Officer, Naval School of Health Sciences (OC)
8901 Wisconsin Avenue, Bethesda, MD 20889-5611

Subj: LOCAL APPROVAL OF CIP STUDY #S-98-L000000-018, "PILOT STUDY, SURVEILLANCE OF BIRTH DEFECTS AMONG US NAVAL HEALTH CARE BENEFICIARIES IN SAN DIEGO COUNTY"

Ref: (a) NSHSBETHINST 6000.41A

Encl: (1) CIP Study #S-98-018

1. Per reference (a), enclosure (1) with supporting documentation is forwarded for your review and information.

2. Local approval for this study was authorized by signature of the Deputy Commander on 23 February, 1998. Approval is documented in committee minutes of the Scientific Review Committee (SRC).

3. Questions should be referred to the Research Program Administrator's Office at (619) 532-8136 or DSN 522-8136.

D. L. Reeves

D. L. REEVES
By direction

two questionnaires regarding patient and partner treatment satisfaction have been shortened to 15 and 5 questions respectively.

3. **NEW BUSINESS**

a. **CIP #S-98-011**, "The Effects of Virtual Reality and Optimized Vestibular Rehabilitation Therapy on Motion Sickness and Other Vestibular Disorders" by LCDR Hoffer. This study will establish a database of patients presenting to the Vestibular Balance Center which will include diagnosis, treatment and follow-up.

This study was unanimously approved by the SRC pending revisions requested by the committees. Local approval by the Commander is recommended per reference (b).

SRC COMMENTS: This registry was approved as written.

CPHS COMMENTS: This project is exempt from CPHS review per reference (f).

b. **CIP #S-98-015**, "The Effect of Autologous Platelet Gel on Seroma Formation in Breast Cancer Surgery" by LCDR Morris. The object of this study is to evaluate in a randomized, prospective manner if platelet gel can seal the tissue flaps created during breast cancer surgery eliminating the need for surgical drains.

This study was unanimously approved by the SRC and CPHS pending revisions requested and budget resolution. Local approval by the Commander is recommended per reference (b).

SRC COMMENTS: The committee reviewed and approved the project pending revisions in December.

CPHS COMMENTS: The committee approved the consent form pending the following revisions: the consent form be written on an eighth grade level, add "duration of treatment" to paragraph 3, add "a surgical drain will be placed and there may be a hematoma or discomfort from arterial stick" to paragraph 6, and rewrite the Justification for Human Subjects at eighth grade level.

ASSIGNED RISK: More than minimal.

b. **CIP #S-98-018**, "Pilot Study: Surveillance of Birth Defects Among U.S. Naval Health Care Beneficiaries in San Diego County" by CAPT Gray, NHRC.

This study was unanimously approved by the SRC pending revisions requested and budget resolution. Local approval by the Commander is recommended per reference (b).

SRC COMMENTS: This is a fully funded registry. The committee requested that the shipboard time be included in the factors, that the investigators be proactive in finding subject population, and that the number of babies aborted due to defects be included.

CPHS COMMENTS: This project is exempt from CPHS review per reference (f).

c. **CIP #S-98-021**, "rSP-C Surfactant in the Treatment of Acute Respiratory Distress Syndrome (ARDS)" by CDR Mull. The objectives of this study are to assess the safety and efficacy of two dose levels in ARDS and to assess the composition and function of surfactant recovered from bronchoalveolar lavage fluid.

This study was unanimously approved by the SRC and CPHS pending revisions requested and budget resolution. Local approval by the Commander is recommended per reference (b).

SRC COMMENTS: This is a proprietary study by Byk Gulden Pharmaceuticals of Germany, being handled in the USA by Covance Clinical and Periapproval Services Inc. Dr. Riffenburgh, the statistician, requested additional information regarding the statistics presented. The company has been contacted for a response.

CPHS COMMENTS: The committee reviewed and approved the consent form pending the following changes: add the name of the pharmaceutical company in paragraph 1, simplify the wording, include bronchoscopy, and define the three groups the patients may participate in paragraph 4, and include that the patient's condition could worsen immediately following drug dosage in paragraph 7. CDR Gubler abstained from voting.

ASSIGNED RISK: More than minimal.

d. **CIP #S-98-023**, "The Safety and Effectiveness of the Episcan 20 Diode Laser System for Depilation" by LCDR Ross. The title is self-explanatory.

This study was unanimously approved by the SRC and CPHS pending revisions requested by the committee. Local approval by the Commander is recommended per reference (b).

REPORT DOCUMENTATION PAGE

Form Approval
OMD No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATE COVERED
	November 1998	New/Final (Jan 97 to Dec 98)

4. TITLE AND SUBTITLE
Active Surveillance Among U.S. Department of Defense Beneficiaries: Report of a Feasibility Study

5. FUNDING NUMBERS
DoD Reimbursible-6423
Program Element:
Work Unit Number:

6. AUTHOR(S)
Bush RA, Gray GC, Smith TC, Gee DE, Honner WK, Lekarev O, Strohl ME

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Naval Health Research Center
P.O. Box 85122
San Diego, CA 92186-5122

8. PERFORMING ORGANIZATION NUMBER:
Tech Doc No: 98-4D

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Office of Naval Research
800 North Quincy Street
Arlington, VA 22217-5660

Chief, Bureau of Medicine and Surgery
Code: BUMED-26
2300 E Street NW
Washington, DC 20372-5300

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTAL NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution is unlimited.

12b. DISTRIBUTION CODE
A

13. ABSTRACT *(Maximum 200 words)*

Birth defects remain the leading cause of infant mortality in the United States and, to date, the Department of Defense (DoD) has no comprehensive monitoring program in place to track birth defects. Having completed a feasibility study on the construction of a birth defects registry in San Diego county, the Naval Health Research Center proposes a DoD-wide, hybrid surveillance system to track birth defects among military members and their dependents.

14. SUBJECT TERMS
Abnormalities-epidemiology; Birth Defects Registries; Fetal Disease; Infant Mortality

15. NUMBER OF PAGES: **83**

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited